Immunization Manual

Interlake Regional Health Authority
Public Health Program

January 2012

Interlake RHA

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Original signed by Shannon Montgomery.

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SECTION I INTERLAKE REGIONAL HEALTH AUTHORITY PUBLIC HEALTH IMMUNIZATION PROGRAM

INTRODUCTION

Background

Immunization Programs within Manitoba are governed under the Communicable Disease Control Branch of Manitoba Health and Healthy Living. The Interlake Regional Health Authority (IRHA) Immunization Program is part of comprehensive communicable disease prevention, control and management and is a core public health service. Recommended immunization programs are based on national and provincial epidemiologic data and consultation within various committees and advisory groups at the regional and provincial levels.

The Immunization Program Manual outlines the provision of immunization services pertaining to:

- Roles of Public Health staff
- Clinical practice
- Immunization documentation
- Vaccine storage and handling
- Management and reporting of adverse events following immunization

The College of Registered Nurses of Manitoba, the provincial licensing body, specifies the standards for professional nursing practice. The Immunization Program Manual's guidelines operationalize these standards of nursing practice.

The Immunization Program Manual is designed to be used in conjunction with the most recent edition of the *Canadian Immunization Guide* and recommendations from the National Advisory Committee on Immunization (NACI). The IRHA Immunization Manual has been adapted in parts from the BC CDC Immunization Manual, available at http://www.bccdc.ca/dis-cond/comm-manual/CDManualChap2.htm

PROGRAM GOAL

The protection of individuals and communities by preventing the spread of vaccine-preventable disease through immunization.

OBJECTIVES

Since the introduction of vaccination programs 50 years ago, the incidence of communicable diseases affecting children has been greatly reduced in Canada. Immunization has saved more lives in Canada than any other health intervention. New vaccines continue to be developed, approved and funded to prevent the death and disease associated with communicable diseases. However, outbreaks of vaccine preventable diseases still occur despite provincially- funded vaccine programs. In order for immunization programs to be successful, high rates of coverage are required among children and adults. The following table outlines the national immunization goals and coverage target rates.

National Immunization Goals and Coverage Targets	
Goals	**Coverage Targets:**
Diphtheria • Eliminate indigenous cases of diphtheria	• 97% of children up-to-date by 2nd birthday • 99% up-to-date by 7th birthday
Tetanus • Maintain absence of neonatal and childhood tetanus	• 97% of children up-to-date by 2nd birthday • 99% up-to-date by 7th birthday
Poliomyelitis • Maintain the elimination of wild indigenous poliomyelitis	• 97% immunized with 3 doses by 2nd birthday • 99% up-to-date by 7th birthday
Measles • Eliminate indigenous measles in Canada	• 97% of children have had 1st dose by the 2nd birthday • 99% of children have had 2nd dose by the 7th birthday
Mumps • Maintain an active prevention program for mumps to minimize serious sequelae	• 97% of children up-to-date by 2nd birthday • 99% up-to-date by 7th birthday
Rubella • Eliminate indigenous rubella infections during pregnancy • Adopt the World Health Organization/Pan American Health organization regional goal to eliminate indigenously transmitted cases of rubella and congenital rubella syndrome (CRS) from Canada by 2010.	• 97% of children by their 2nd birthday (1 dose) • 97% of children by their 7th birthday. • 97% of adolescents 14 to 16 years of age. • 99% of susceptible women prior to hospital discharge.
Invasive Haemophilus influenza type b • Achieve and maintain the absence of preventable cases of invasive Haemophilus influenza type b by 1997.	• 97% of children up-to-date by 2nd birthday

Pertussis • Reduce morbidity and mortality related to pertussis infection.	• 95% of infants by 3 months of age. • 95% of infants/children by 7 months of age. • 95% of children by their 2nd birthday. • 95% of children by their 7th birthday. • 85% of adolescents by their 18th birthday • Provinces & territories should replace adult Td vaccine with Tdap vaccine.
Hepatitis B • Reduce the prevalence of indigenously acquired chronic hepatitis B infections in children and young adults by 90% by 2015	• 95% of populations immunized (targeted in universal programs) • Each province & territory has a policy to provide Hep B to high risk individuals as outlined in the Canadian Immunization Guide.
Varicella • Reduce illness and death due to complications from varicella through immunization	• 85% of children up-to-date by 2nd birthday • 85% of susceptible children by 7th birthday • 85% of susceptible adolescents by their 17th birthday

Invasive Pneumococcal Disease (IPD)
• Reduce illness and death due to pneumococcal disease through immunization
	• 90% of children by their 2nd birthday
	• With a single dose of pneumococcal polysaccharide vaccine in:
	  ○ 80% of adults = 65 years of age
	  ○ 95% of residents in long-term care facilities

Invasive Meningococcal Disease • Reduce illness and death due to *Neisseria meningitidis* serogroup C through immunization	• 100% of *N. meningitidis* serogroup C close contacts of cases • 95% of high-risk groups for *N. meningitidis* serogroup C disease • 97% of children by their 2nd birthday • 90% of susceptible adolescents by their 17th birthday
Influenza • To prevent serious illness caused by influenza and its complications, including death.	• 95% coverage of residents of long-term care facilities and staff who have extensive contact with residents • 80% coverage of persons aged = 65 years of age • 80% coverage of persons < 65 years of age with high risk conditions • 80% coverage of health care workers • 100% coverage of vaccinators • 80% coverage of household contacts of people at high risk

Sources: Public Health Agency of Canada (2008). Final Report of Outcomes from the National Consensus for Vaccine-Preventable Diseases in Canada; *Canada Communicable Disease Report,* volume 34 – March 2008

Public Health Agency of Canada (2002) Canadian National Report on Immunization, 1996: General Goals and Targets. *Canada Communicable Disease Report* volume 23S4 – May 1997

The IRHA Public Health program will aim to:

1. Develop strategic plans to attain and maintain regional goals and objectives towards the National Immunization Goals and Coverage targets.
2. Protect children against vaccine-preventable diseases by providing immunization services at the earliest appropriate age.
3. Maintain the immunization status of children by reinforcement doses as recommended throughout the preschool and school age years.
4. Provide immunization for adults as recommended and determined by individual client circumstance.
5. Provide specific immunization to targeted high-risk groups.

INDICATORS

1. Immunization coverage rates for 1 year olds, 2 year olds, 7 year olds, 11 year olds and 17 year olds as provided by the Manitoba Immunization Monitoring System (MIMS) Annual Reports.
2. Percentage of eligible Interlake students immunized within the school based immunization program.
3. Number of influenza vaccinations provided annually as monitored by the influenza campaign statistic gathering.
4. Percentage of IRHA employee influenza vaccinations as self-reported on influenza consent forms.
5. Number of cold chain breaks.

IMMUNIZATION PROGRAM PRINCIPLES

The IRHA Public Health Program will:

1. Maintain a comprehensive Immunization Program Manual to ensure prescribed standards of practice and consistent delivery of services are met.
2. Ensure an Immunization Competency Program is in place for all immunization staff. It is mandatory that all Public Health Program vaccine providers complete an immunization competency program prior to administering biological products.
3. Provide all immunization staff with an orientation to the safe provision of immunization services.
4. Develop strategic plans to attain and maintain the National Goals for routine immunization against vaccine-preventable diseases within the provincial criteria for publically-funded vaccines.
5. Input all immunizations provided by public health into the Manitoba Immunization Monitoring System.

6. Maintain proper vaccine storage and handling as outlined by the current National Vaccine Storage and Handling guidelines.
7. Report adverse events following immunization to Manitoba Health and Healthy Living.
8. Monitor coverage rates via the MIMS Annual Report, IRHA School Immunization Program statistics, IRHA Community Influenza Campaign statistics.

LEVELS OF RESPONSIBILITY

Guideline: Roles and responsibilities for Public Health staff are described in other documents by the Interlake RHA (Public Health Program Policy and Procedure Manual). This section pertains specifically to levels of responsibility for immunization services. It is also recognized that physicians and nurses are bound to standards of practice as defined by their own profession. Those standards will not be included in this section.

Medical Officer of Health

The Medical Officer of Health (MOH) will actively participate in the development and ongoing evaluation of IRHA immunization programs and policies. The MOH will serve as a resource to the Regional Immunization Coordinator and Public Health staff on immunization questions, concerns, and case management. The MOH will review and provide recommendations for further immunization on all adverse events following immunization. The MOH will also serve as a liaison for the IRHA to Manitoba Health and Healthy Living (MHHL) on immunization issues.

Public Health Program Manager

The Program Manager provides leadership and support for communicable disease and immunization services within the IRHA. In conjunction with the MOH and the Regional Immunization Coordinator, the Program Manager reports activities and results of immunization programs. The Program Manager is responsible for communication with other related agencies and organizations regarding immunization issues.

Regional Immunization Coordinator

The Immunization Coordinator will actively participate in the development and ongoing evaluation of IRHA immunization programs and policies. The Immunization Coordinator will provide education and direction to Public Health Staff regarding immunization and program implementation. The Immunization Coordinator will assist with case management and adverse event following immunization management. The Immunization Coordinator will facilitate collection and compilation of information and statistics regarding the immunization program of the IRHA. The Immunization Coordinator will update public health and immunization staff with current information as provided by MHHL and the National Advisory Committee on Immunization.

Public Health Nurse

The Public Health Nurse (PHN) will actively participate in vaccine-preventable communicable disease control through education and delivery of immunizations as recommended by the Manitoba Routine Immunization Schedule. The PHN will also assist in the planning, coordination, and implementation of school and community based immunization clinics in her/his community area. The PHN will confer with the Immunization Coordinator and/or MOH regarding immunization issues.

School Immunization Clinic Planner

The School Immunization Clinic Planner will plan, coordinate and implement the school based immunization clinics in her/his area of responsibility. The School Clinic Planner will work with the Immunization Coordinator, the PHN's, the Immunization Clerks, Interlake schools, and parents to facilitate the school based immunization program. The School Clinic Planner will participate in statistics collection to assist the Immunization Coordinator in providing coverage rates on school based immunization programs.

Immunization Nurse

Under the direction of the Immunization Coordinator and working with the community area PHN(s) and School Immunization Clinic Planner, the Immunization nurse provides health assessment, education and clinical services with the goal of ensuring optimal immunization status of the targeted population. The nurse will actively participate in the implementation of school and community based immunization services.

Immunization Clerk

Under the direction of the Immunization Coordinator and working with the community area PHN(s), the Immunization Clerk provides clerical support with the goal of ensuring optimal immunization status of the targeted population. The Immunization Clerk is responsible for contributing to the maintenance and updating of immunization records on the Manitoba Immunization Monitoring System (MIMS) for clients. The Immunization Clerk coordinates all paperwork and MIMS inputting associated with school based programs. The Immunization Clerk actively participates to ensure the smooth flow of school immunization and community flu clinics. The Immunization Clerk assists in the collection and maintenance of statistical data of immunization rates of school and community clinics.

PUBLIC HEALTH ACT AND THE IRHA IMMUNIZATION PROGRAM

The IRHA is responsible for the coordination of health services based on the needs of the population in the Interlake. These health services include communicable disease control and prevention.

Each Manitoba Regional Health Authority is responsible for implementing legislated services found in the Public Health Act. Immunization services are part of communicable disease control and disease prevention. The provision of such services makes public health staff an integral partner in improving health within communities.

IMMUNIZATION COMPETENCY

All Public Health vaccine providers will have completed an immunization competency program prior to providing immunization services. An on-line immunization competency program, available at http://www.advancingpractice.com/p-68-immunization-competencies-education-program.aspx has been developed by the Canadian Paediatric Society in association with the Public Health Agency of Canada and Health Canada**.** This Immunization Competencies Education Program provides participants with an in depth review of the Immunization Competencies for Health Professionals, a national consensus on the education and training required by immunization providers. The purpose of the immunization competency program is to assist immunization providers to fulfill their roles as vaccine advocates, educators, and service providers. A vaccine provider must demonstrate the attitudes, knowledge, and clinical skills necessary to provide safe and effective immunization programs.

The Regional Immunization Coordinator is responsible for ensuring that the immunization program orientation reflects evidenced-based guidelines and current Canadian public health practice. The Immunization Coordinator also ensures that Public Health staff who provide immunizations are competent through the Interlake RHA Immunization Competency Program criteria:

- Public Health Nurses will complete the Immunization Competencies Education Program prior to providing service.
- RN's who provides care within in the Immunization Program will complete the IRHA Immunization Competency Education Session prior to providing service or an on-line refresher package for returning RN's.
- Current certification for cardio-pulmonary resuscitation (CPR) training. Community nurses are required to re-certify according to the provincial standard.
- Completion of Anaphylaxis Management training.

SCHOOL AND COMMUNITY BASED IMMUNIZATION PROGRAM

IRHA immunization services will be planned, coordinated and implemented by each community area team, following the guidelines set out in the Immunization Manual. Each community has different population needs and resources that need to be taken into consideration, for a successful program outcome. This manual, the current Canadian Immunization Guide and the Regional Immunization Coordinator will provide support and guidance to the field staff for specific immunization related issues.

TERMS AND DEFINITIONS

The following section reviews basic concepts and terms regarding immunization.

Active immunity: is protection which is produced by the person's own immune system. This type of immunity is usually long-lasting. Active immunity occurs when the immune system develops antigen specific humoral and cellular immunity. Active immunity can be obtained either by acquiring the natural disease or by receiving a vaccine.

Adjuvants: chemical substances used to increase the effectiveness of certain vaccines. Salts of aluminum such as hydroxide and phosphate are adjuvants used for certain vaccines.

Adverse event following immunization (AEFI): local or systemic side effects experienced after the use of a substance such as an immunizing agent. Most adverse reactions are mild and self-limited. There may be adverse reactions that are serious in nature and that may require medical assessment and treatment.

Allergen: any substance (protein, antigen, or other substance) that triggers or results in an allergic reaction.

Allergy: an acquired hypersensitivity to a substance (allergen) that does not normally cause a reaction in most persons. The reaction is due to the release of histamine or histamine-like substances from injured cells.

Anaphylaxis: is rapid, severe and life threatening response that occurs when a person is exposed to a substance to which he/she has previously been exposed. The reaction can occur without warning and within seconds to minutes after the ingestion, injection, or exposure of certain substances ie/ serum, vaccine, antibiotics, foods, insect bites, etc.

The main features of anaphylaxis are:

> Skin: itchy, uticarial rash (>90% of cases), progressive angioedema of the face or mouth. The angioedema may follow signs and symptoms such as pruritus, tearing, nasal congestion, facial flushing.
> Respiratory: sneezing, coughing, wheezing, labored breathing, bronchospasm, upper airway swelling possibly leading to airway obstruction.
> Cardiovascular: hypotension, shock, hemodynamic collapse.

Antibodies: proteins produced by the plasma cells (derived from B-cells) respond to antigen once it had entered the organism. Examples of antibody types: IgG, IgM, IgA, IgD, IgE.

Booster: additional vaccine doses given to an individual after the primary series in order to maintain antibody levels.

Contraindication: any condition which renders immunization improper of undesirable. This includes anaphylactic reaction to previous exposure to vaccine or components of vaccine or certain conditions for specific vaccines (ie/ pregnancy with MMR).

Diluents: a specific substance used and recommended for the dilution of a vaccine or a drug. The diluent is used to avoid chemical or physical incompatibility and inactivation of a vaccine/drug.

Diphenhydramine HCL (Benadryl): antihistamine, antiemetic and antispasmodic. Indicated in the emergency treatment of anaphylaxis. Blocks histamine receptors and follows administration of epinephrine.

Epinephrine (adrenaline): used pharmaceutically as a sympathomimetic, a cardiac stimulant, a pressor substance, or to relax bronchial smooth muscles. Widely considered the drug of choice in emergency treatment of severe allergic reactions or anaphylaxis.

Immune response: A defense system in the human body comprised of immune cells and tissues responsible for rejecting foreign microbes or objects such as tumors; inactivating viruses, bacteria and other organisms; neutralizing toxins; and performing other defense functions. The immune system can also memorize its previous exposure to certain microbes and respond to fight against a recurrence. For example, once you have had measles, you never get it again.

Many factors may influence the immune response to vaccination. These include the presence of maternal antibodies, the nature and dose of the antigen, the route of administration, age of the recipient, and co-existing disease.

Immune system: the immune system is a complex defense and regulatory system of interacting cells whose main goal is to identify foreign substances and develop a defense against them.

Immunity: natural or artificial ability to fight off disease.

Immunization: procedure of introducing a live, killed or partial component of a vaccine to trigger a person's immune system for the purpose of protection against a disease.

Immunology: the study of immunity to diseases, particularly the reaction (beneficial or adverse) between antigens-antibodies.

Passive immunity: is protection by antibodies produced by an animal or human and transferred to another human, usually by injection. Passive immunity often provides effective protection against some infections, but this protection disappears over time, usually a few weeks or months.

The most common form of passive immunity is that which an infant receives from its mother. Antibodies are transported across the placenta during the last one to two months of pregnancy. As a result, a full-term infant will have the same antibody profile as its mother. These antibodies will protect the infant from certain diseases for up to a year. Protection is better against some diseases (ie/ measles, rubella, tetanus) than others (ie/polio, pertussis).

Precaution: Conditions (ie/ moderate or severe illness with or without fever) not listed as contraindications, but should be carefully considered in determining the benefits and risks of administering a specific vaccine. If the benefits are believed to outweigh the risks (ie/ during an outbreak, or foreign travel) the vaccine should be given.

Preservatives: trace amounts of chemical used to prevent bacterial growth and/or to stabilize the vaccine. Examples of these chemicals are thimerosal and neomycin.

Primary immunization series: an initial series of vaccinations designed to induce sufficient immunity against a disease or several diseases. The series may be followed by an additional booster dose(s) to give a secondary immune response.

Toxoids: a deactivated form of a bacterial toxin which has been chemically processed so that it is still able to stimulate the production of protective immunity; ie/ tetanus and diphtheria toxoids. The toxoid itself is not toxic.

Vaccine: is an immunizing agent composed of a whole or fraction of a microorganism (ie/ bacteria, virus, parasite).

SECTION II

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SECTION II A – COPY OF INFORMED CONSENT FOR IMMUNIZATION POLICY

(found in the General Administration Policy and Procedure Manual)

POLICY TITLE	POLICY NUMBER
Informed Consent for Immunization	GA-10-15
	DATE OF ORIGINAL APPROVAL
	February 6, 2007
	APPROVED BY:
	Senior Management Team
MANUAL/SECTION	DATE OF REVIEW / REVISION
Public Health Program – Immunization Manual Communicable Disease Control General Administration – Client Care	February 6, 2007
	PAGE(S)

POLICY:

The need to obtain informed consent prior to a health care intervention is based on the principle that a client is autonomous and has the right to determine what happens (or does not happen) to his or her body.

The immunization provider is responsible for ensuring that the client or his/her substitute decision-maker has been provided access to sufficient information and been given the opportunity to ask questions in order to provide an informed consent.

DEFINITIONS:

Immunization (or vaccination): a method of providing protection against a disease caused by an infection. Immunization can be administered orally, intramuscularly, intradermally or subcutaneously.

Vaccine: refers to all biological substances used for active or passive immunization of humans, including live and inactivated viral and bacterial vaccines, toxoids, immune globulins, antitoxins and antivenoms.

Substitute decision-maker: a designated person to make health-care decisions on behalf of an individual who does not have the capacity to make health care decisions. These rights may be exercised by:

- a parent or court-appointed guardian if the child is under 16 years of age, unless the health professional administering the immunizing agent reasonably

believes the child is able to understand the nature and effect of the information and is able to appreciate the consequences of a decision; or
- a parent or court-appointed guardian if the child is 16 years of age or older, if the health professional administering the immunizing agent reasonably believes the child is not able to understand the nature and effect of the information or able to appreciate the consequences of a decision;
- a proxy appointed by the individual under the Health Care Directives Act;
- a committee appointed under the Mental Health Act if the Committee has the power to make health care decisions on the individual's behalf (ie: Public Trustee or private committeeships);
- a substitute decision-maker for personal care appointed for the individual under The Vulnerable Persons Living with a Mental Disability Act if the exercise of rights relates to the powers and duties of the substitute decision maker;
- nearest relative to the individual (spouse, son or daughter, other).

*Further detailed information regarding substitute decision-makers is available in the Informed Consent Policy GA-10-10, General Administration Manual/Client Care

GUIDELINES:

The process of obtaining informed consent is a requirement supported by the Canadian National Advisory Committee on Immunization (NACI), the College of Physicians and Surgeons of Manitoba and the College of Registered Nurses of Manitoba.

1. Criteria for valid consent for immunization:
    - Must be given voluntarily;
    - The person consenting must have the legal and mental capacity to consent;
    - The consent must authorize the particular immunization(s) as well as the care giver e.g. staff nurse, PH staff;
    - The consent must be informed (presented with access to sufficient information and allowed the opportunity to ask questions).

2. Consent when a person does not have capacity to make health care decisions:
    - Consent must be given by a substitute decision-maker who is able to understand the benefits and the risks of immunization(s).

3. Consent is required for each vaccine being administered. However, it is possible to consent to a series of immunizations (e.g. 3 doses of hepatitis B vaccine):
    - The number of doses should be clearly stated in the Manitoba Health fact sheet, Childhood Immunization Consent, Adult Immunization Record form, or Consent for Annual Influenza Immunization form, or communicated verbally;

- Consent should be "updated" between doses if necessary. This means the provider should communicate any important new information that could alter a decision to be immunized. This could include changes to the vaccine formulation e.g. now contains an additional antigen, or a change in the risk for adverse reactions based on reactions occurring after a previous dose, or reminder of upcoming immunization program.

4. Duration of Consent
    - Consent should not normally be considered valid more than 6 months after it is given.

PROCEDURE:

1. The process of obtaining informed consent for immunization should include an opportunity for review of:
    - the risks of the disease(s) and complications;
    - the benefits and risks to the client of receiving or not receiving the vaccine;
    - details about the vaccine route and schedule(s);
    - vaccine content
    - choices of vaccines where applicable;
    - contraindications (e.g. due to allergies, age, pre-existing medical conditions, concurrent medications or treatments, recent receipt of certain immune globulins or vaccines, etc.);
    - any reactions to previous vaccinations, if applicable;
    - benefit to the community of the client where applicable; and
    - how to manage common side effects, including when to consult with a health professional (common and serious side effects as defined in the Immunization Fact Sheet, current Canadian Immunization Guide, vaccine product monograph);
    - immunization information will be documented and recorded in the Manitoba Immunization Monitoring System (MIMS).

2. Informed consent may be given in writing or verbally.

3. Absence of a parent or the substitute decision-maker at the time of the vaccine administration:
    - In situations where, in the professional opinion of the immunization provider, the client is not able to give informed consent and their substitute decision-maker will be absent at the time of vaccine administration, written or verbal consent may be obtained by forwarding all the necessary documents e.g. fact sheet(s), consent form, and other related documents if needed, to an appropriate substitute decision-maker.

- In circumstances when the consent form has not been returned or returned with incomplete information e.g. no signature, the immunization provider should make a reasonable attempt (minimum of 2 attempts using various strategies e.g. phone calls, repeat mailings of related documents, fax, or re-sending documents through school) to contact the parent or the substitute decision-maker for verbal consent (or refusal).

Two examples of this situation are:

Residents of personal care homes or other chronic care facilities:

- The consent may be obtained on admission, depending on facility's policy.
- Each year, the facility should communicate with the client or their substitute decision-maker (either in writing or verbally, depending on the facility's policy) regarding any proposed immunizations to ensure there are no changes and the consent is still valid.

School based immunization programs:

- Immunization providers should obtain consent from the parent or the legal guardian prior to the start of the immunization program. In circumstances when the consent form has not been returned or returned with incomplete information e.g. no parental signature, the immunization providers should make a reasonable attempt (as defined above) to contact the parent or the legal guardian for verbal consent (or refusal).

4. For children in the permanent custody of Child and Family Services, the assigned case worker signs the consent form. For children in temporary custody or in foster care, the parent/legal guardian signs the consent form. The assigned case manager should facilitate the process of getting the consent form signed. Any further inquiries regarding who grants informed consent for immunization with regard to children in Child and Families Services care should be directed to such agency.

DOCUMENTATION:

The process of obtaining informed consent (in writing or verbal) including refusal of immunization must be documented.

- The client or their substitute decision-maker's signature is not required on the "Manitoba Health Adult Immunization Record Form" or the "Interlake Regional Health Authority (IRHA) Influenza and Pneumococcal Consent Form" or the "Manitoba Health Influenza and Pneumococcal Vaccine Surveillance Form".

The immunization provider must document that informed consent has been obtained.

- A signature is preferred when related documents are forwarded to the client's parent or guardian or other substitute decision-maker to obtain informed consent. To facilitate provision of written informed consent, the IRHA provides an IRHA "Immunization Consent Form" and/or the MB Health "Adult Immunization Record Form".

A consent form may be evidence that a client or their substitute decision-maker provided a legally sufficient consent to a procedure, but only if the consent form reflects what actually occurred.

The current "Manitoba Health Influenza and Pneumococcal Vaccine Surveillance Form" can be used as long as the check box on the form indicates that informed consent has been obtained and the immunization provider gives his/her signature.

A client's medical chart (health record) may be used to document the process to obtain informed consent to or the refusal of a vaccine.

The Childhood Immunization Consent, Adult Immunization Record, Interlake Regional Health Authority Immunization Consent Form or Influenza and Pneumococcal Vaccine Surveillance form can be considered a "client record" in whole or part.

EQUIPMENT/SUPPLIES:

Manitoba Health vaccine fact sheets are available for clients or their legal decision-maker to give informed consent. These fact sheets reflect the suggested minimum information required to be given so that a person can make an informed decision.

- The fact sheets are available at the Manitoba Health, Communicable Disease Control web site: http://www.gov.mb.ca/health/publichealth/cdc/
- Copies of fact sheets are also available from Material Distribution Agency (MDA), Manitoba Health's official publication warehouse and distribution centre. Orders may be faxed at (204) 942-6212 or e-mailed at InformationResources@gov.mb.ca

Immunization documentation forms including MIMS records and client health records as appropriate for age of client and site where service provided.

SECTION II B – GENERAL IMMUNIZATION GUIDELINES

1.0 IMMUNIZATION SCHEDULES

- Immunization providers follow the recommended schedule outlined by the current Manitoba Immunization Schedule as outlined by the **Manitoba Immunization Schedules Reference Guide for Health Professionals** (see 8.0 – Resources, at the end of this section) – or refer to Manitoba Health Communicable Disease Control Branch Site at http://www.gov.mb.ca/health/publichealth/cdc/fs/irg.pdf
- Adhere as closely as possible to recommended vaccine schedules. Recommended ages and intervals between doses of multi-dose antigens provide optimal protection or have the best evidence of efficacy.
- Age for immunization relates to actual birth date, not corrected gestational age.
- There is no minimum weight for commencing immunization.
- Use each client contact as an opportunity to review the immunization status and administer all vaccines for which the client is eligible.
- Assess for vaccine eligibility by assessing the client's age, health status, lifestyle risk factors, and contact with individuals at risk of vaccine preventable disease.
- Client is eligible for all vaccines indicated for his/her birth cohort. If a client was eligible for a vaccine when a program was introduced but did not receive the vaccine, he/she remains eligible for the vaccine.
- Individuals who have started an immunization series in another jurisdiction as part of a universal program that is not currently included in the Manitoba provincially funded vaccine program will have the series completed at no cost.
- Immunization status is determined by documentation of immunization or proof of having had the disease (ie/ immunization record or laboratory documentation of immune status), A verbal history of immunization or disease alone may not be reliable. All children and adults lacking written documentation of immunization should be started on a primary immunization schedule as appropriate for their age.
- Interruption of a recommended vaccine series does not require starting the series over again, regardless of the interval elapsed. Individuals should be immunized to complete the appropriate schedule for their current age.
- By contrast, doses given at less than the **minimum** interval may result in less than optimal antibody response and should not be counted as part of a primary series.
- Vaccines should not be administered at less than the minimum intervals or earlier than the minimum age.

- Special consideration with the teen booster of Tdap (tetanus, diphtheria, acellular pertussis) vaccine: the Tdap booster can be administered safely at intervals ≥ 18 months since the last tetanus and diphtheria containing vaccine. (Halperin, S. A. et al. (2006).How soon after a prior tetanus-diphtheria vaccination can one give adult formulation tetanus-diphtheria- acellular pertussis vaccine? The Pediatric Infectious Disease Journal, 25 (3), 195-200)

2.0 CONTRAINDICATIONS AND PRECAUTIONS FOR IMMUNIZATION

- A contraindication is a condition in a client that increases the risk for a serious adverse event. A vaccine should not be administered when a contraindication is present.
- In general, the only contraindication applicable to all vaccines is a history of an anaphylactic reaction to a previous dose of vaccine or vaccine component.
- Severe immunosuppression and pregnancy are contraindications to live vaccines only.
- A precaution is a condition in a client that might increase the risk for a serious adverse reaction or might compromise the ability of the vaccine to produce immunity. In these situations, further assessment and a risk/benefit analysis is needed.
- Assess every client for contraindications and precautions prior to any immunization. The following factors should be considered:
  - History of anaphylactic reaction to any antigens or components contained in the vaccine.
  - Adverse events previously experienced following receipt of same vaccine
  - Past and current health state, specifically immune system conditions.
- With live vaccine administration, assess:
  - History of receipt of immune globulin, blood transfusion or blood product in the past year.
  - Receipt of a live vaccine within previous 4 weeks
  - Pregnancy, or planning pregnancy in the next month.
- Assess for history of Guillain-Barre syndrome (GBS) with onset within 8 weeks of a previous immunizations. Subsequent doses of the same vaccine should be only given if the benefit of vaccination outweighs the potential risk of recurrence of the GBS if vaccine is given.
- The client's family physician may also be consulted regarding contraindications and precautions to immunization.

2.1 Severe allergy to vaccine components

- Allergic reaction may be caused by:
  - Vaccine antigen
  - Residual animal protein (ie/ egg protein)
  - Antimicrobial agents (ie/ neomycin, polymyxin)

- Preservatives
- Stabilizers
- Other vaccine components

2.1.1 Egg allergy

- Clients with histories of anaphylactic reaction to eggs should generally not receive vaccines containing residual amounts of egg protein (ie/ influenza vaccines).
- Egg allergy is **not** a contraindication to MMR vaccine. MMR vaccine may contain trace quantities of egg protein, but the amount is not felt to be enough to cause an allergic reaction.
- Prior egg ingestion is not a prerequisite for immunization with an egg-containing vaccine.
- The inability to eat eggs for any other reason but severe allergy is not a contraindication to immunization with an egg-containing vaccine.

2.1.2 Latex allergy

- Assess clients for a previous anaphylactic reaction to latex when the biological product vial stopper or needle shield contains latex.
- Latex is a sap from the commercial rubber tree. Latex is processed to form natural rubber latex and dry natural rubber.
- Dry natural rubber is used in some syringe plungers, vial stoppers and needle shields.
- It is possible the allergenic proteins could be introduced into the product being administered during immunization and cause an anaphylactic reaction.
- Synthetic rubber and synthetic latex do not contain natural rubber or natural latex and, therefore, do not contain the impurities linked to allergic or anaphylactic reactions.
- The most common type of latex sensitivity is contact-type allergy, usually as a result of prolonged contact with latex-containing gloves. Contact dermatitis is **not** a contraindication to immunization with a latex-containing vaccine.
- If a person reports an anaphylactic allergy to latex, do not administer vaccines supplied in vials or syringes that contain natural rubber. Refer to client's family physician for further consultation.

2.2 Conditions that are <u>not</u> contraindications to immunization

2.2.1 Antibiotics

- Antibiotics have no effect on response to most inactivated or live vaccines used in Canada.

- Exceptions:
  - Live oral typhoid vaccine should be delayed until at least 24 hours after antibiotics active against Salmonella typhi.
  - Live attenuated varicella vaccine may have reduced effectiveness if given concurrently with antivirals effective against herpes viruses.

2.2.2 Convalescence from or exposure to an infection:

- No interference with response to vaccine.
- No increased risk of adverse events following immunization.
- E.g., a child who has been exposed to varicella may be safely immunized with varicella vaccine. A child who has had varicella disease immediately prior to presenting for 12 month immunizations may be safely immunized with all vaccines (including varicella).

2.2.3 Acute illness with or without fever:

- Note: Minor, moderate, or severe acute illness, with or without a fever, is **not** a contraindication to immunization.
- No interference with response to vaccine.
- No increased risk of adverse events following immunization.
- Minor illnesses such as teething, stomach upsets, and the common cold, with or without fever, frequently occur in young children and are **not** a contraindication to immunization. Such infections do not increase the risk of adverse events following immunization and do not interfere with immune responses to vaccines. While there is a theoretical risk that the occurrence of systemic adverse events may complicate the medical management of the other acute illness or that events associated with the acute illness may mistakenly be thought to be vaccine-related adverse events, the potential risk is much less important than the risk associated with missing an opportunity to give a recommended vaccine.

2.2.4 Breastfeeding:

- There are no contraindications or precautions to immunization of either the lactating mother or the breastfeeding infant.
- After immunization of either the mother or her infant, there is:
  - No reduction in maternal or infant immune response to vaccines
  - No increase in the risk of adverse events for either the mother or her infant.

2.2.5 History of allergy that does not involve vaccine or its components:

- It is safe to immunize people with any of the following:
  - Non-specific allergies
  - Environmental allergies
  - Family history of allergies
  - Administration of allergy shots (desensitization therapy for allergy)
  - Allergies to commonly used antibiotics
    - Exception: vaccines containing neomycin and/or polymyxin are contraindicated in individuals with IgE-mediated allergies to these antibiotics.

2.2.6 Family history of adverse reactions to vaccines:

- Adverse reactions to vaccines are not known to be inherited.
  - Exception: a family history of an overwhelming infection or fatality after administration of a live vaccine may suggest inheritable severe immunodeficiency, which should be ruled out before administering live vaccines.

3.0 IMMUNIZATION OF SPECIAL POPULATIONS

There are a variety of health conditions that place an individual at increased risk for certain vaccine preventable diseases. There are also a few groups of individuals (e.g., health care workers, new Canadians) who require special consideration of their immunization status and who are eligible for certain vaccines.

Please consult the current *Canadian Immunization Guide* and the supplemental NACI recommendations for vaccine specific statements at the following website: www.phac-aspc.gc.ca/naci-ccni/index-eng.php when providing immunizations to the following individuals:

- Pregnancy and breastfeeding
- Infants born prematurely
- Patients in health care institutions
- Immunocompromised persons
- Persons with neurologic disorders
- Persons with bleeding disorders
- Travellers
- Persons new to Canada

When assessing a high risk individual's eligibility for certain vaccines, it is important to assess overall immunization status and current state of health. Unless contraindicated (i.e., live vaccines for immune-suppressed individual), ensure routine vaccines are included in the client's immunization plan. When a client presents with an identified health condition or is identified as being a member of a select population:

- Ascertain the details of client's specified health condition (if applicable).
- Assess the client's immunization and communicable disease history.
- Refer to recommendations relating to the client's medical condition or population in the Canadian Immunization Guide.
- Ensure routine immunizations are up to date. There is no indication to re-administer a primary immunization series except for Hematopoietic stem cell transplantation recipients.
- Assess the individual's eligibility for additional recommended vaccines.
- Assess for any contraindications to any recommended vaccines.
- If recommended, consult the client's medical specialist prior to administration of live vaccines (i.e., varicella and MMR).
- For more information on specific vaccines, refer to the Manitoba Health Communicable Disease Control Branch Site at http://www.gov.mb.ca/health/publichealth/cdc/div/schedules.html or consult the Regional Immunization Coordinator or the Medical Officer of Health.

4.0 IMMUNIZATION OF RESIDENTS/PATIENTS IN HEALTHCARE FACILITIES

Residents and patients in healthcare facilities should be offered immunizations to prevent or reduce illness as well as reduce the spread of vaccine preventable diseases. Standing orders for immunizations in facilities, along with clear guidelines should be available to staff.

- Whenever possible, obtain an immunization history. Adult immunizations given within Manitoba since 2000 will be recorded in the MIMS database.
- Annual influenza vaccination is recommended for all residents of long-term care facilities.
- Residents of long-term care facilities should be immunized with pneumococcal vaccine on admission, if there is no documentation of previous immunization. Routine re-immunization is not recommended but should be considered for those of any age at highest risk of invasive infection (Canadian Immunization Guide, p. 273)
- Tetanus diphtheria booster can be provided every 10 years.

5.0 REQUESTS FOR NON-ROUTINE IMMUNIZATIONS

Public Health Nurses can provide non-provincially funded vaccines on request to clients according to the following guidelines:

- The Public Health Nurse (PHN) is able to meet IRHA Public Health program and other community demands for service provision.
- Clients are able to procure vaccine at no cost to the IRHA or Manitoba Health.
- The PHN does not provide pre-travel health assessment services. The PHN will advise the client to seek travel health advice from an accredited travel medicine clinic in the province.
- The PHN can administer client-purchased vaccines to clients not meeting Manitoba Health eligibility criteria, provided that the client has purchased the vaccine via prescription from their physician or an accredited travel health clinic, and consent for immunization has been signed.

Non-provincially funded vaccines could include (but are not limited to):

- Hepatitis A
- Hepatitis B (born before 1989)
- Hepatitis A/B combination
- Human Papillomavirus
- Meningococcal
- Pneumococcal
- Rotavirus
- Varicella

An immunization record will be completed for the client and consent forms are forwarded to the MIMS clerk for inputting and filing according to office practice.

6.0 IMMUNIZING ALONE

A nurse can immunize alone in a school or community clinic or home environment provided the following conditions are met:

- Immunization is indicated.
- A phone is easily accessible to activate emergency medical services and person other than the nurse can call 911.
- The nurse has a current immunization competency (has completed the immunization module and is a currently practicing immunization nurse).
- The nurse has a current CPR certification.

- The personal safety of the nurse is not at risk.
- An anaphylaxis kit is present.
- The immunizations are structured such that the nurse would be monitoring no more than three people at any given time.

7.0 IMMUNIZATION RECORDS

Immunization registries play a key role in ensuring that individuals receive all recommended immunizations and avoid those that are unnecessary. These registries also permit efficient evaluation of the immunization status of specific individuals, groups or the population overall.

Manitoba's immunization registry, the Manitoba Immunization Monitoring System (MIMS) became functional province-wide in 1988, making it the first such registry in Canada. At that time, immunizations provided to children born after 1980 were recorded in the MIMS electronic database. Adult immunizations were added to the registry in the year 2000.

Immunization events are captured in MIMS in two ways: publicly-funded immunizations administered by physicians are entered into the system via the physician billing system; all other immunizations, such as those provided by public health nurses, are recorded by data entry staff in the regions. The goal is to have all immunizations administered in Manitoba recorded in MIMS.

MIMS captures information related to an immunization event, including type of vaccine administered, date of administration and service provider.

7.1 MIMS Access

- Prior to persons gaining access the MIMS database, an authorization form must be submitted on their behalf. The Public Health Program Manager will submit an Information Technology Account Request Form requesting MIMS access to either inquiry or updating privileges.
- The request will be approved by the IT Manager and will be forwarded to Manitoba Health for MIMS access.
- MB Health MIMS Manager will provide a system user-id and temporary password to access the MIMS database.
- MIMS training will be provided by Interlake RHA MIMS Trainer for either inquiry or updating access.
- Every person using MIMS must have their own account (i.e. their own password).
- MIMS users can access the MIMS training manual at http://www.gov.mb.ca/health/publichealth/surveillance/strategies.html

- MIMS immunization tariff codes and MIMS forms can be found on the Manitoba Health website under Public Health, Epidemiology and Surveillance at http://www.gov.mb.ca/health/publichealth/surveillance/forms.html

7.2 Immunization Record Request

- Immunization information may be shared for the purposes of providing client services, and upon the request of the client or his/her parent/guardian, provided that Personal Health Information Act (PHIA) compliance is achieved.
- Manitoba Health recommends MIMS users to request MIMS certificates as the preferred response to requests for immunization records (refer to instructions in the MIMS user manual on the MB Health website referenced under 1.2: MIMS access above).
- MIMS certificates are produced on the weekend following the request entry, and mailed at the beginning of the following week.
- Manitoba Health does not discourage the printing of the immunization history screen if there is an urgent need for an immunization record, provided PHIA compliance is achieved, as the ultimate goal is to ensure that accurate information is provided as required.
- All requests for immunization information provided must be recorded on the **IRHA Request for Client Information** (see 8.0 – Resources) and stored in a binder in the Public Health Office.

8.0 RESOURCES

- *Manitoba Immunization Schedules – Reference Guide for Health Professionals* available at http://www.gov.mb.ca/health/publichealth/cdc/fs/irg.pdf
- *IRHA Request for Client Information* available on the IRHA Shared Server "Departments on Irha.mb.ca (B:)" at B:\PublicHealth\Immunization

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SECTION III – ADMINISTRATION OF BIOLOGICAL PRODUCTS

1.0 POLICY:

The PHN shall follow the IRHA Public Health Policy and Procedure Manual for the administration of immunizations to infants and children (PH-2-20-7) and adults (PH-2-20-9). The PHN will provide immunization following provincial guidelines for infants, children and adults according to the "**Manitoba Immunization Schedules – Reference Guide for Health Professionals"** (see 13.0 – Resources).

2.0 CONSIDERATIONS FOR THE SCHEDULING AND ADMINISTRATION OF MULTIPLE IMMUNIZATIONS:

- Guideline 7 of the National Guidelines for Immunization Practices (Canadian Immunization Guide, 2006) states **"Administer all vaccine doses for which a recipient is eligible at the time of each visit."** Adherence to this standard of practice will avoid a missed opportunity for immunization and the inherent possibility of the individual contracting a vaccine preventable disease. Individuals should be fully immunized at the appropriate age. The practice also results in fewer periods of discomfort for the client and fewer office visits with decreased time and cost factors for both clients and health care providers.
- There are no contraindications to giving multiple injections of vaccines at the same clinic visit. There is no increase in side effects, reduced vaccine effectiveness, or reduced parental compliance.
- When two biological products are to be administered, although not necessary, it is preferable to use different limbs. When administering two biological products in the same limb, separate the two injections by a distance of at least 2.5cm (1") so that local reactions are unlikely to overlap.
- Rapidly inject the biological product (unless the viscosity of the product is prohibitive or the manufacturer suggests slower injection e.g. immune globulin products).
- Give vaccines that are known to cause more stinging and/or pain last.
- If live virus vaccines are not administered concurrently, separate their administration by at least 4 weeks.

3.0 PROCEDURE – PREPARATION FOR ADMINISTRATION OF BIOLOGICAL PRODUCTS

- Refer to "Immunization Provider Reference Sheet" (vaccine specific) – (see 13.0 – Resources)
- Ensure that a current anaphylaxis kit is readily available for use whenever immunization is being administered.
- Prior to immunizing, obtain informed consent (refer to IRHA Informed Consent for Immunization Policy GA-10-15) using the Immunization Consent Form (see 13.0 Resources) and appropriate vaccine fact sheets, available at Manitoba Health Communicable Disease Control Branch Site at http://www.gov.mb.ca/health/publichealth/cdc/div/schedules.html
- Complete client assessment:
    - Review client's record to determine which vaccines client is eligible for at the current visit (verify client immunization history via the parent/guardian and MIMS data base).
    - Ask the parent/guardian about all relevant contraindications and precautions to receiving the vaccine, including history of anaphylaxis and history of fainting.
- Prepare the vaccine product according to the vaccine product monograph.
    - Prepare necessary materials (i.e. sterile syringe, safety engineered needle, alcohol swab, cotton ball, band-aid, sharps container)
    - Consider the 7 "rights" of medication administration (right product, right client, right dose, right time, right route, right reason, and right documentation)
    - Check the characteristics of the product to be administered (i.e. expiry date, appearance, irregularities in product or presentation, such as a damaged vial, or particulate matter)
    - If product is in multi-dose vial, check date that vial was opened (as recorded on vial) and ensure product within manufacturer specifications for expiry of opened product.

4.0 DRAWING UP BIOLOGICAL PRODUCTS IN VIAL PRESENTATION

- Wash hands or cleanse with a sanitizer.
- Remove the plastic cap covering the vial.
- Cleanse the surface of the rubber stopper using a cotton pad/swab moistened with 70% isopropyl alcohol. Allow to air dry.
- Gently swirl the vial immediately before removing each dose to ensure that the contents are fully dispersed.
- For a product in a "ready to go" liquid presentation, draw into the syringe a volume of air equal to the quantity of biological product to be removed.

- For lyophilized, or freeze-dried products (e.g., MMR) having to be reconstituted, the diluent acts as the air in the syringe so there is no need to draw air into the diluent syringe.
- Hold/place the vial right side up and insert the needle through the centre of the rubber stopper.
- Slowly inject the air or diluent from the syringe.
- If the biological product was reconstituted, gently swirl the vial to ensure the contents are fully dispersed.
- Hold the vial upside down and withdraw the required quantity of biological product into the syringe.
- Remove the needle from the vial and expel the air bubble(s).
- It is not necessary to change needles between drawing up the biological product into the syringe and immunizing the client. Change the needle only if it is damaged, or becomes contaminated.
- If it is the first entry into a multi-dose vial, record the date (include day, month and year) on the label of the vial.
- Immediately return multi-dose vials to the refrigerator/biological cooler.

5.0 DRAWING UP BIOLOGICAL PRODUCTS IN AMPOULE PRESENTATION

- Gently swirl the ampoule immediately before removing the contents to ensure that the contents are fully dispersed.
- Tap the ampoule lightly to ensure that the contents are in the lower part of the ampoule.
- Using a swab moistened with isopropyl alcohol, wipe the neck area of the ampoule prior to opening to prevent bacterial contamination of ampoule contents.
- Break the neck of the ampoule using cotton pad/unopened alcohol swab.
- Withdraw the contents of the ampoule away from you, using a sterile syringe and 25-gauge needle. It is not necessary to change needles between drawing up the biological product into the syringe and administering it to the client.
- Discard the ampoule into a sharps container.
- Expel the air bubble(s) from the syringe.

6.0 STANDARD PRECAUTIONS

- Gloves are not required when administering biological products unless the vaccinator has open hand lesions or will come into contact with potentially infectious body fluids.
- Wash hands well or use alcohol hand sanitizer between clients (using a quarter-size amount of alcohol hand sanitizer, distribute evenly rubbing on hands for 15 seconds; allow to dry).
- Only safety-engineered needles should be used.

- With safety needles engage safety mechanism immediately following administration of the biological product.
- Immediately discard needle and attached syringe in sharps container. Place sharps container so as to avoid reaching or having to reach in front of the client. Caution should also be taken so that the sharps container cannot be reached by children in the clinic setting.
- Do not empty used needles and syringes from one sharps container to another.
- Report needle stick injuries immediately to supervisor for consideration of possible post-exposure immunoprophylaxis. Follow worksite health and safety protocol. All immunization providers should have completed a full series of hepatitis B vaccine.

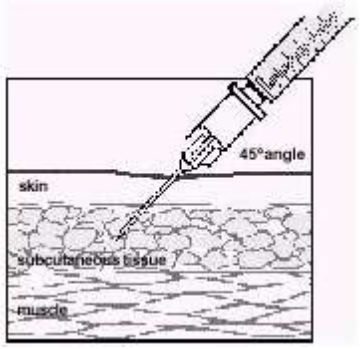
7.0 INJECTION SITES, NEEDLE SIZE AND POSITIONING

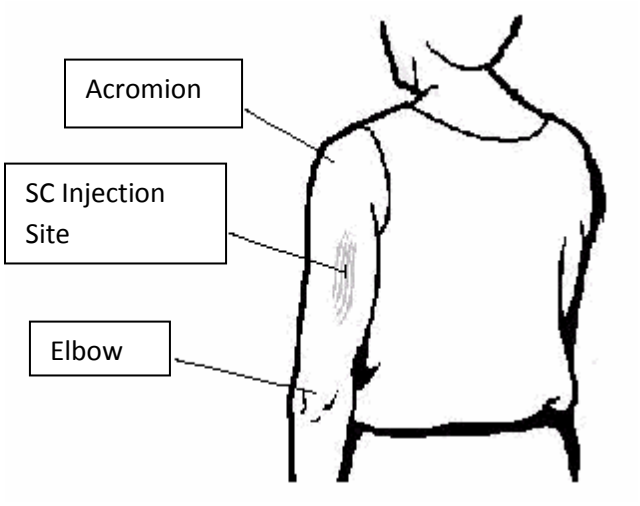
- Use clinical judgment to select appropriate injection site and needle size. This assessment is based upon:
    - client's age
    - volume of biological product to be administered
    - viscosity of biological product
    - adequacy of muscle mass
    - recommended route of administration for the biological
    - number of products to be administered.

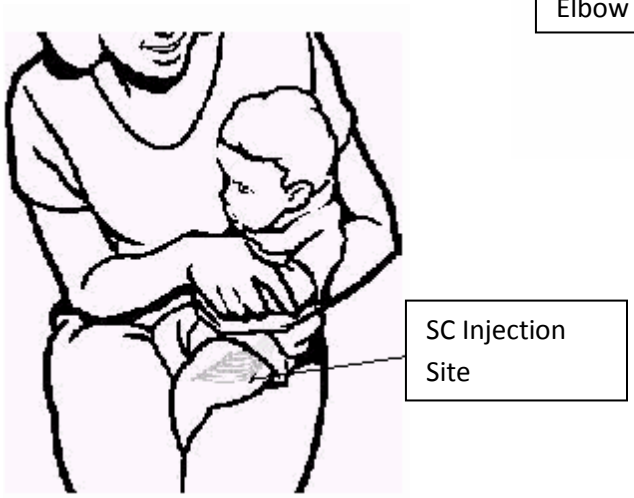
- After selecting the appropriate injection site, inspect the skin's surface over the site for bruises, scars, or inflammation. Palpate site for masses, edema, or tenderness. If any of these are found at the injection site, do not use the site, as there might be interference with absorption of the biological.
- Correct positioning of the client is important in ensuring the biological product is administered in the correct site. Instruct the parent /guardian to hold the child such that the immunization site is clearly visible to the immunizer and the child is sufficiently restrained to prevent as much movement as possible during the immunization. See the "Comforting Restraint with Immunization" (California Department of Health Services) for comforting and restraining techniques (see 13.0 – Resources).
- Rapid injection is recommended for all vaccines injected subcutaneously or intramuscularly. It is not recommended for more viscous biological products such as immune globulin preparations or those for which the manufacturer recommends a slower administration.

7.1 Needle size and sites for subcutaneous (SC) injection

Use a 25 – 27 gauge 5/8” – 7/8” needle for subcutaneous injections. Sites for subcutaneous injection are the lateral aspect of the upper arm and the fatty area of the anterolateral thigh. The thigh is the site of choice for infants <12 months of age and the upper outer triceps area is recommended for all individuals ≥12 months.







7.1.1 Subcutaneous (SC) Injection Procedure

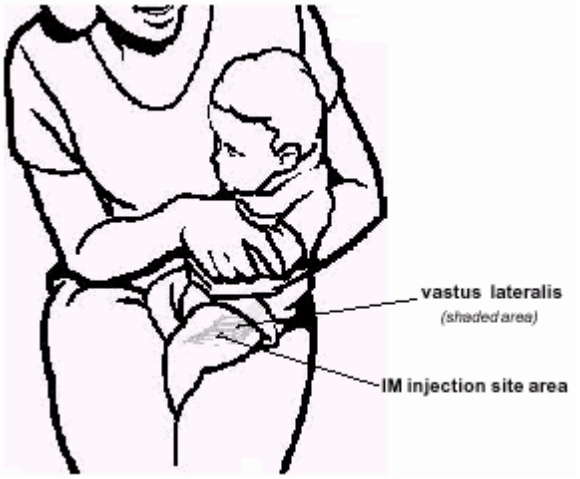
- Use correct length and size of needle. Bunch a skin fold of fatty tissue at site with thumb and forefinger.
- Clean the site with alcohol swab. Allow the skin to air dry prior to injection to avoid burning sensation on insertion of the needle.
- Insert the needle quickly with the bevel up into the tissue at a 45˚ angle.
- For an obese client, use a longer needle and inject at a 90˚ angle to reach SC tissue.
- Release the skin, and rapidly inject the vaccine. **NOTE:** Aspiration is not recommended as there is no data to document its necessity prior to the SC injection of biologic products.
- Remove the needle quickly at the same angle it was inserted, and apply pressure to the injection site with a dry cotton ball. Apply band-aid over injection site.
- Discard needle/syringe unit into sharps container.

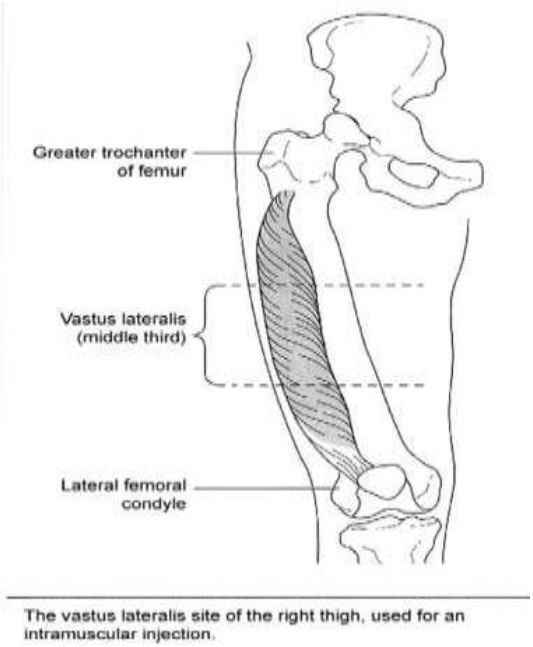
7.2 Needle size, sites and procedure for intramuscular (IM) injection

- Use a needle length sufficient to reach the largest part of the muscle. This is to prevent the biological being deposited in subcutaneous tissue and to decrease or prevent abscess formation. The use of longer needles has also been associated with less redness and swelling at the immunization site than occurs with shorter needles.
- For infants, toddlers, and older children a 7/8”- 1” needle is recommended, depending on the muscle size and the amount of subcutaneous tissue.
- For adolescents and adults, a 1 – 1 ½˝ needle is usually used.
- Use a 22 to 25 gauge needle depending on the viscosity of the biological product. A larger bore needle (e.g., 22 gauge) may be required when administering viscous products such as immune globulin preparations.
- The IM site of choice for infants less than 12 months of age is the vastus lateralis (anterolateral thigh). It should also be considered for older children with a small deltoid muscle mass. For children > 12 months of age and for adults, the preferred site is the deltoid muscle. When the deltoid muscle is used for children > 12 months of age, first assess the adequacy of the muscle mass.

7.2.1 Vastus lateralis (anterolateral thigh) site

- This site is used for both IM and SC injections.
- When immunizing an older child or adult, position client in a supine, side lying, or seated position.
- When immunizing an infant, have the parent/caregiver hold the infant in a "cuddle" or semi-recumbent position on their lap.

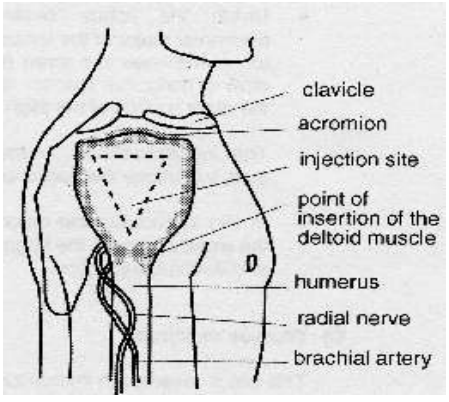




The vastus lateralis site of the right thigh, used for an intramuscular injection.

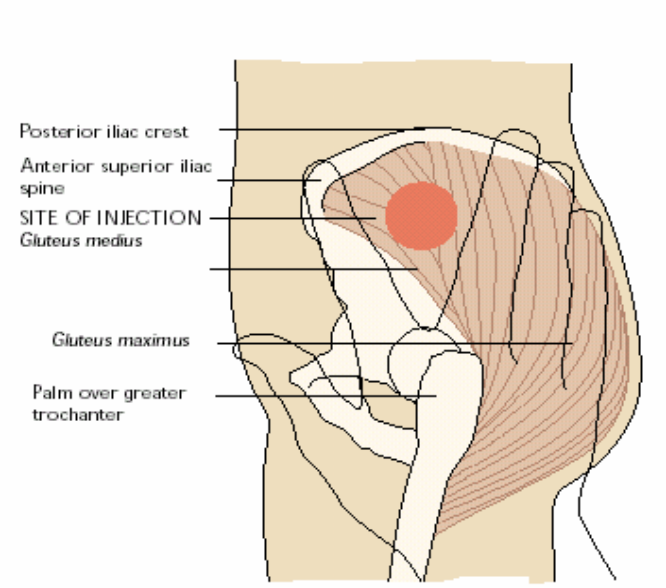
7.2.2 Deltoid site

- This site is used for IM injections only.
- Have the child sit sideways on the lap of the parent/caregiver. The injection arm should be held close to the infant's body while the other arm is tucked behind the parent's/caregiver's back.
- To help in relaxing the muscle during the injection, the older client may be seated with their elbow bent and their forearm resting on the arm of a chair or their lap.
- Define the site by drawing a triangle with its base at the lower edge of the acromion and its peak above the insertion of the deltoid muscle. The injection site is in the center of the triangle.



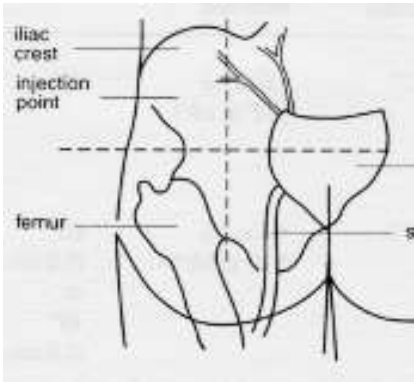
7.2.3 Ventrogluteal site

- Do **not** use this site for vaccine administration.
- The ventrogluteal site is the preferred site for the IM injection of large volumes of immune globulin preparations (e.g. Ig, HBIg, TIg, RabIg).
- This site can be used in those over 7 months of age.
- This muscle is accessible in the supine, prone, and side lying position.
- The right hand is used for locating the site on the left hip; the left hand is used for locating the site on the right hip.
- Place heel of the hand over the greater trochanter of the client's hip with wrist almost perpendicular to the femur. Point the thumb toward the client's groin and the fingers toward the client's head. Point index finger to the anterior superior iliac spine, and extend the middle finger back along the iliac crest toward the buttock. The index finger, the middle finger, and the iliac crest form a V-shaped triangle. The injection site is the center of the triangle.



7.2.4 Dorsogluteal site

- Do **not** use this site for vaccine administration, as it is less immunogenic for a number of vaccines, including hepatitis B and rabies vaccines. The dorsogluteal site is only to be used for the IM injection of large volumes of immune globulin preparations (e.g., Ig, HBIg, TIg, RIg).
- This site should **only** be used in individuals over five years of age.
- Place client in a prone, side lying, or standing position.
- Encourage a posture that will provide muscular relaxation and reduce discomfort (i.e. turning toes inward when prone, flexing the upper leg at hip and knee when lying on the side, flexing knees and leaning upper body against a support when standing).
- Define the site by dividing the buttock into 4 quadrants. The injection site is the centre of the upper outer quadrant.
- Direct the needle anteriorly (i.e., if the client is lying prone, direct the needle perpendicular to the table's surface, not perpendicular to the skin plane).



7.2.5 Intramuscular (IM) Injection Procedure

- Use correct length and size of needle.
- Clean the site with alcohol swab. Allow the skin to air dry prior to injection to avoid burning sensation on insertion of the needle.
- Insert the needle quickly and firmly into the muscle at a 90˚ angle.
- If client's muscle mass is small, grasp body of muscle between thumb and forefinger before and during injection.
- Rapidly inject the vaccine. **NOTE:** Aspiration is not recommended as there is no data to document its necessity prior to the IM injection of biologic products. The Canadian Immunization Guide (2006) indicates that there are no studies that

have assessed the need for aspiration prior to IM injection of vaccine in relation to vaccine safety. The Advisory Committee on Immunization Practices (2006) has stated that aspiration before injection of vaccines is not required because no large blood vessels exist at the recommended injection sites. Taddio et al agree by stating "the sites commonly used for vaccine injections are devoid of large blood vessels, and aspiration is no longer regarded as necessary." (Canadian Medical Association Journal – November 2010)

- Remove the needle quickly at the same angle it was inserted, and apply pressure to the injection site with a dry cotton ball. Apply band-aid over injection site.
- Discard needle/syringe unit into sharps container.

7.3 Site and needle size for intradermal injection

- Use a 1 ml TB syringe and 27 gauge needle of 1/2" length.
- The usual site for intradermal injections is the flexor (anterior) surface of the forearm.
- Have client rest their arm on a firm surface, forearm turned up.
- Because of the decreased antigenic mass administered with ID injections, attention to technique is essential to ensure that the material is not injected subcutaneously.

7.3.1 Intradermal (ID) Injection Procedure

- Use correct length and size of needle.
- Clean the site with an alcohol swab. Allow the skin to air dry prior to injection to avoid burning sensation on insertion of the needle.
- Gently stretch the skin the selected region between the thumb and index finger.
- Insert the needle with the bevel facing upwards, at a constant angle of 5˚ - 15˚ until the bevel disappears (the needle tip can be seen through the skin).
- Without aspirating, inject the biological product slowly with controlled pressure.
- A white elevated wheal (bleb) 6 – 8 mm in size should appear (resembles the appearance of a mosquito bite).
- The size of the wheal is not completely reliable, but if a lot of liquid runs out at the time of injection and there is no wheal, repeat the procedure using the other arm.
- Remove the needle quickly and sponge the injection site with a dry cotton ball – do not massage the area. A drop of blood may be seen – this is normal.
- DO NOT apply a band-aid after a TB skin test, as the band-aid can mark the skin and confuse the skin test readings.
- Discard needle/syringe unit into sharps container.

7.4 Injection Site, Volume and Equipment Guidelines

Route	Site	Age	Needle Size/ Length	Maximum Volume/site
Intramuscular (IM)	Deltoid	Infants (> 12 months) & Children Adolescents & Adults	23 – 25 g 5/8 – 1” 23 – 25 g 1 – 1 ½” (22 g for immunoglobulin products)	1 ml depending on the size of the muscle. 1 – 3 ml
	Vastus Lateralis (thigh)	Infants (< 12 months) Children (1 – 5 yrs) Children (5 – 18 yrs) Adults (> 19 yrs)	25 g 7/8 – 1” 22 – 25 g 1” 22 – 25 g 1 – 1 ½” 22 – 25 g 1 – 1 ½”	1 ml 1 ml 1 – 3 ml 5 ml
	Ventrogluteal (site of choice for large volume)	Children (1 – 5 yrs) Children (5 – 18 yrs) Adults	22 – 25 g 1” 22 – 25 g 22 g 1 – 1 ½” 22 g 1 ½”	0 – 2 ml 0 – 2 ml 0 – 4 ml
	Dorsogluteal (only as a very last resort)	Children (> 5 years) Adults	22 g 1” 22 g 1 – 1 ½”	0 – 2 ml 0 – 4 ml
Subcutaneous (SC)	Normal site is slightly lateral to insertion of deltoid. Other sites acceptable.	All ages	25 g 5/8”	.5 – 1 ml
Intradermal (ID)	Usually flexor surface of forearm.	All ages	25 g 3/8” or ½”	.1 ml

Children > 12 months of age require IM injections in the deltoid muscle - NACI guidelines (2006)
***** A dose of > 3 ml is usually divided and given at two different sites. A volume of solution > 3 ml can cause muscle tissue displacement and possible tissue damage. Dividing the dose for > 3 ml is acceptable safe practice.

8. 0 CLIENT OBSERVATION FOLLOWING IMMUNIZATION

- Advise recipients of any biological product (i.e., vaccine, immune globulin, TB skin test) to remain under supervision for at least 15 minutes after immunization; regardless of whether or not they have had the particular product previously. **Thirty (30) minutes is a safer duration when the person has other documented allergies. If a person has had a prior allergic reaction to the biological product or a component of the biological product, immunization should occur in a physician clinic.**
- The risk of fainting is the more common reason to keep biological product recipients under observation.
- Directly observe any client with symptoms such as pallor or sweating (possibly pre-syncope) in the clinic setting. Assist these clients to sit or lie down until symptoms resolve.
- Where recipients of a biological product choose not to remain under supervision after immunization, inform them (or their parent/guardian) of the signs and symptoms of anaphylaxis and instruct them to obtain immediate medical attention should symptoms occur.

9.0 MANAGEMENT OF PAIN & ANXIETY BEFORE AND DURING IMMUNIZATION

- The pain associated with immunization is a source of distress for children, their parents and those administering the injections.
- Minimizing pain during childhood vaccinations can help to prevent distress and the development of needle fears. Health care providers must establish an environment that promotes trust and mutual respect.
- Some individuals who are particularly concerned about pain associated with immunization may be interested in the use of topical anesthetics (section 10).

9.1 Prepare Parents and Children

- Encourage parents/caregivers and children (if possible) to prepare for the immunization in advance by using evidence-based strategies to minimize pain and distress in children during the immunization experience. (provide parents with the HELPinKIDS Information Sheet: A Guide for Parents, Caregivers and Children on How to Reduce Vaccine Injection Pain in Children (see 13.0 – Resources).
- Do not give false reassurance (i.e., “it won’t hurt“). Honest reassurance is “it may hurt a bit, but I think you can handle it.”
- Discourage threats, shaming, or manipulation from the child’s parent/guardian or caregiver. When a parent threatens a child, the most helpful response is to offer empathy to the parent.

9.2 Structure the environment

- If a parent presents with more than one child, immunize the most anxious one first (usually the eldest), even if the parent thinks otherwise.
- Provide privacy and prepare the immunization ahead, if possible, always out of sight of the child. If the child asks to see the needle, explain you will show it *after* the procedure.
- Describe what you plan to do, thereby displaying respect for a child's right to know, confidence in their ability to manage, and interest in addressing concerns. Threatened loss of control is a factor in needle fear.
- Provide limited, realistic choices and let the child decide (e.g., "Would you like to use your right or left arm?"). Offering realistic choices creates a setting where the child can maintain some personal control and contributes to an atmosphere of mutual respect.
- Infants, children and teens should not be positioned supine for the procedure.
- Infants and children should be held by a parent/caregiver in a position that is most comfortable for them and their parent. Although the exact mechanism underlying the reduction to pain associated with this positioning is unknown, it may involve a reduction of anxiety, which in turn reduces the perception of pain.
- Encourage mothers to breastfeed infants during vaccinations.
- Alternatively, infants can be given sugar water with a syringe or pacifier right before the injection.
- Do not have the child secured until you are ready to administer the vaccine. The longer the child is restrained the greater the loss of personal control and hence increased anxiety. The goal of restraint is not to overpower the child, but to assist the child to remain as still as possible for the procedure. See the "Comforting Restraint with Immunization" (California Department of Health Services) for comforting and restraining techniques (see 13.0 – Resources).
- Manage the time and set limits. If the child cannot calm him or herself, acknowledge their effort and offer a rest period.

9.3 Calming and distraction techniques

- Distraction involves taking the child's attention away from the injection procedure. It is effective for children of all ages. Regardless of the type of distraction, the more the child is involved in the distraction, the lower their pain.
- Work with the parent to use age-appropriate distraction techniques such as the use of toys, party blowers, reading, music, use of pinwheels or soap bubbles.
- Use non-procedural talk (favourite movie, video game) with older children
- Slow, deep breathing has a physiologic calming effect and can, at minimum, limit anxiety escalation.
- Maintain a positive attitude.

9.4 Uncooperative Child or Adolescent

- A child or adolescent who firmly refuses immunization by a Public Health Nurse, despite several verbal attempts to secure the youth's compliance for immunization, will not be physically restrained by the provider. The parent/guardian of the child may choose to restrain their child for the purpose of immunization. The provider may proceed with the immunization only if it is safe to do so by her/his judgment.
- In a school setting, the provider will document a refusal of immunization on the appropriate form and refer to a Public Health Clinic.

10.0 USE OF TOPICAL ANAESTHETICS

- Topical anesthetics such as EMLA (eutectic mixture of local anesthesia consisting of 2.5% lidocaine and 2.5% prilocaine) may be used to decrease the pain associated with immunization for children of all ages.
- Topical anaesthetics are available from a pharmacy without a prescription; must be applied up to 1 hour prior to injection.
- Two doses/sites may be needed, depending on the number of immunizations being given. Specify the injection site(s) to the parent/caregiver.
- Studies have demonstrated that EMLA does not affect the immunologic response to MMR, DTaP-IPV-Hib (Pentacel), or hepatitis B (Recombivax).

11.0 MANAGEMENT OF FEVER AND PAIN FOLLOWING IMMUNIZATION

- Inform client (or parent /guardian) about expected reactions to each biological product administered.
- Advise parents that child may cry or be fussy at home following immunization. Suggest parents:
    - Give acetaminophen (see 11.1- 'Fever management' for appropriate dosages)
    - Apply a clean, cool, damp washcloth for 15 to 20 minutes over the immunization site(s)
- For more information regarding comforting their child after immunization, refer to "After the Shots…What to do if your child has discomfort" (see 13.0 – Resources).
- Instruct client (or parent / guardian) to contact health care provider if concerned about reaction or about any adverse event that occurs following immunization. See Section V: Adverse Event Following Immunization.
- Local and systemic reactions may follow use of biological products. Common reactions to biological products are usually mild, self-limited, and without permanent sequelae. They are intrinsic to the immunizing antigen or some

component of the biological product. These reactions can safely be managed with symptomatic treatment.

- Local reactions include pain, redness and swelling at the injection site. These reactions tend to occur within a few hours of the injection, and are common with inactivated vaccines that contain adjuvants (e.g., DaPT/IPV/Hib). Crying and irritability in infants and young children are likely responses to pain at the site of injection.
- The body's response to injected proteins can also affect heat regulation and produce fever within a few hours of vaccination.
- Systemic reactions are more generalized events and include fever, rash, malaise, myalgia, and headache. These reactions are more common following the administration of live attenuated vaccines (e.g., measles, mumps and rubella vaccines, and varicella vaccines) that must replicate in order to produce immunity. The systemic reactions represent symptoms produced from that replication, and are similar to a mild form of the natural disease.
- When the immunizing agent is a live attenuated vaccine, inform parents that systemic adverse events tend to occur later than those following the administration of inactivated vaccines. For example, for a measles-mumps-rubella-containing vaccine, fever may occur 5 – 30 days after vaccination, most commonly within 7 –14 days. With a varicella vaccine, fever may occur within 0 – 42 days, most commonly between 14 and 27 days after immunization.

11. 1 Fever Management

- When fever is suspected, it is preferable to use a thermometer to measure temperature accurately.
- Recommend acetaminophen for use in managing fever and pain. Its use is preferred to that of ibuprofen. Acetaminophen has an overall safer drug interaction and precaution profile as compared to ibuprofen.
- Acetylsalicylic acid (ASA) is not recommended for children because of its associated risk of Reye syndrome.
- Prophylactic administration of antipyretic drugs at the time of vaccination should not be routinely recommended since antibody responses to several vaccine antigens may be reduced. (The Lancet, volume 374, Issue 9698, pp 1339-1350).
- There are no supporting clinical studies for the prophylactic use of acetaminophen in children prone to febrile seizures. In fact prophylaxis in high risk children has been shown to be ineffective.
- Acetaminophen may be given at a dosage of 10 - 15 mg/kg, four to five times daily, not to exceed five doses or 65 mg/kg in 24 hours. Advise parents not to continue use beyond 48 hours unless specified to do so by a physician. Advise parents to initiate this dosage regimen when there are symptoms of fever and/or pain shortly after immunization.

- The dosage guidelines in the following table will provide an effective but non-toxic serum concentration level based on average child weight. The single dose is calculated to provide 10 -15 mg of acetaminophen per kilogram of body weight. Advise parents to read the label on the product they are using and be aware of the concentration of medication.

Acetaminophen Dosage Guidelines

Weight (kilograms)	Weight (pounds)	Single Dose Acetaminophen
3.0 – 3.9 kg	6 – 8.5 lbs	40 mg
4.0 – 5.4 kg	8.5 – 11 lbs	60 mg
5.5 – 7.9 kg	12 – 17 lbs	80 mg
8.0 – 10.9 kg	17.5 – 23 lbs	120 mg
11 – 15.9 kg	24 – 35 lbs	160 mg

For children over 15.9 kg (35 lbs), give acetaminophen according to age as directed on the medication bottle.

12.0 DOCUMENTATION

- The immunization provider will document the administration of the biological product on the client's immunization consent form. This information will include:
  - Client information (name, date of birth, Manitoba health number)
  - Date of immunization
  - Name of biological product
  - Name of the product manufacturer
  - Tariff code
  - Lot number
  - Dose
  - Route of administration
  - Anatomical site
  - Name and title of immunization provider
- Document on the consent form any recommended biological products that were not given (ie/declined or contraindicated).
- School notification of immunization will be sent home to parent/guardian following immunization (see 13.0 – Resources).
- Notification of Influenza Immunization will be given to clients following immunization at the community influenza immunization clinics (see 13. 0 Resources).
- Complete the Childhood Immunization Record at Community Health Clinic visits and give to parent/guardian.

- Forward immunization consent form to MIMS clerks for inputting into MIMS system.

13.0 RESOURCES

- *Manitoba Immunization Schedules* – Reference Guide for Health Professionals available at http://www.gov.mb.ca/health/publichealth/cdc/fs/irg.pdf
- *Immunization Provider Reference Sheets* – available on the IRHA Shared Server "Departments on Irha.mb.ca (B:)" at B:\PublicHealth\Immunization
- *Immunization Consent Forms* available on the IRHA Shared Server "Departments on Irha.mb.ca (B:)" at B:\PublicHealth\Immunization\Consent forms generic
- *Comforting Restraint with Immunization* (California Department of Health Services) available on the IRHA Shared Server at B:\PublicHealth\Immunization\\Vaccine administration communication tools
- *HELPinKIDS Information Sheet*: A Guide for Parents, Caregivers and Children on How to Reduce Vaccine Injection Pain in Children available on the IRHA Shared Server at B:\PublicHealth\Immunization\\Vaccine administration communication tools
- *After the Shots…What to do if your child has discomfort* available on the IRHA Shared Server at B:\PublicHealth\Immunization\\Vaccine administration communication tools
- *School Immunization Programs – Notification of Immunization* (triplicates for Grade 4 programs, Grade 6 program) – example found on the IRHA Shared Server "Departments on Irha.mb.ca (B:)" at B:\PublicHealth\Immunization
- *Notification of Influenza Immunization* – available on the IRHA Shared Server "Departments on Irha.mb.ca (B:)" at B:\PublicHealth\Immunization\Notice of Immunization

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SECTION IV – MANAGEMENT OF ANAPHYLAXIS IN A NON-HOSPITAL SETTING

1.0 ANAPHYLAXIS

1.1 Description

- Anaphylaxis is a potentially life-threatening IgE-mediated reaction that results from the sudden systemic release of mast cells and basophil mediators. Within 10 minutes, increased vascular permeability allows transfer of as much as 50% of the intravascular fluid into the extravascular space. As a result, hemodynamic collapse might occur rapidly with little or no cutaneous or respiratory manifestations.
- While anaphylaxis is extremely rare, every immunization carries an associated risk of producing an anaphylactic reaction. The estimated annual reported rate of anaphylaxis ranges from 0.4 to 1.8 reports per 1,000,000 doses of vaccines distributed in Canada.
- The more rapidly anaphylaxis occurs after exposure to an offending stimulus, the more likely the reaction is to be severe and potentially life-threatening.
- Anaphylaxis often produces signs and symptoms within minutes of exposure to an offending stimulus, but some reactions might develop later (e.g. > 30 minutes after exposure). Since 20% of anaphylaxis episodes follow a biphasic course with recurrence of the reaction after a 2 – 9 hour asymptomatic period, hospitalization is recommended for monitoring. The presentation of the second phasic reaction may be as pronounced as that of the initial anaphylactic episode.

1.2 Definitions

Urticaria (hives): raised, often itchy, wheals on the surface of the skin.

Angioedema: a swelling similar to hives, but the swelling is beneath the skin rather than on the surface. The swellings are called welts. The welts usually occur around the eyes and lips. They may also be found on the hands, feet, and throat.

Bronchospasm: constriction of the air passages of the lung by spasmodic contraction of the bronchial muscles.

Biphasic: two distinct phases of an anaphylactic reaction. The second phase reaction occurs 2 – 9 hours after the initial episode.

1.3 Presentation

- Changes develop over several minutes and usually involve at least two body systems (affecting the skin, respiration, circulation). Unconsciousness is rarely the sole manifestation of anaphylaxis. It occurs only as a late event in severe cases.
- Anaphylaxis occurs as part of a continuum. Even when there are mild symptoms initially there is the potential for progression to a severe and even irreversible outcome. Fatalities during anaphylaxis usually result from delayed administration of epinephrine and from severe respiratory complications, cardiovascular complications, or both. **There is no contraindication to epinephrine administration in anaphylaxis.**
- Urticaria and angioedema are the most common manifestations of anaphylaxis.
- Features of early or mild anaphylaxis may include swelling and hives at the injection site, sneezing, nasal congestion, tearing, coughing, and facial flushing. These symptoms are generally associated with minimal dysfunction.
- Features of moderate to severe anaphylaxis include obstructive swelling of the upper airway, marked bronchospasm, and hypotension.

Table l: Frequency of occurrence of signs and symptoms of anaphylaxis

Signs and symptoms	Approximate frequency
Cutaneous	**90%**
Generalized urticaria (hives) and/or angioedema	85 – 90%
Flushing	45 – 55%
Pruritus (itchiness) with or without rash	2 – 5%
Respiratory	**40 – 60 %**
Upper airway angioedema	50 – 60%
Dyspnea (difficulty breathing), wheeze	45 – 50%
Rhinitis (nasal congestion)	15 – 20%
Dizziness, syncope, hypotension	**30 – 35%**
Abdominal	
Nausea, vomiting, diarrhea, cramping pain	25 – 30%
Miscellaneous	
Headache	5 – 8%
Substernal (chest) pain	4 – 6%
Seizure	1- 2%

2005 Journal of Allergy and Clinical Immunology, 115, S483-523.

1.4 Assessment

Assess:

- Level of consciousness (impairment might reflect hypoxia)
- Upper and lower airways [hoarse cry/voice, stridor (a high-pitched noisy sound occurring during inhalation or exhalation), cough, wheezing, or shortness of breath]
- Respiratory rate
- Pulse rate – assess for rapid, weak, irregular pulse; examine for pallor or cyanosis around perioral area
- Skin – observe for facial flushing, itching, hives or welts
- Gastrointestinal system - nausea, vomiting, or diarrhea
- Injection site (s) – observe for redness, swelling, hives

In general, the sooner the onset, the more rapid and severe the anaphylactic reaction.

1.5 Action of epinephrine

- Action of epinephrine:
    - Counteracts the histamine induced vasodilation
    - Increases heart rate and cardiac contractility to increase oxygenated blood flow to vital organs
    - Acts on smooth muscles of bronchial tree thereby reducing bronchospasm
    - Suppresses body's immune response (slows down histamine cascade)

- When epinephrine is administered intramuscularly (IM), it acts on beta adrenergic receptors found in the skeletal vasculature causing vasodilation. The IM route will generally tend to have a faster rate of absorption of the epinephrine.
- Thus, when IM immunization is given and epinephrine is indicated, it should not be administered into the same muscle mass as the immunization as it will produce vasodilation locally at the site increasing vascular permeability of the offending antigen.
- Intramuscular epinephrine injections into the thigh (vastus lateralis) have been reported to provide more rapid absorption and higher plasma epinephrine levels in both children and adults than intramuscular or subcutaneous injections administered into the arm. Superiority of blood flow to the vastus lateralis and the cutaneous vasoconstrictive properties of epinephrine are believed to account for this difference.
- If administration into a thigh is problematic, epinephrine may be administered IM into the deltoid muscle of children ≥ 12 months of age and to adults.
- Side effects of excessive doses of epinephrine pose little danger but can add to the person’s distress by causing palpitations, tachycardia, flushing, and headache. Cardiac dysrhythmias can occur in older adults but are rare in otherwise healthy children.

2.0 ANAPHYLAXIS VERSUS FAINTING, ANXIETY, ALLERGIC REACTION, OR INJECTION SITE REACTION

Anaphylaxis must be distinguished from fainting (vasovagal syncope), anxiety and breath-holding spells, which are more common and benign reactions. The lack of hives, a slow, steady pulse rate, and cool pale skin distinguishes a vasovagal episode from anaphylaxis.

2.1 Fainting and anxiety reaction

- During fainting, the individual suddenly becomes pale, loses consciousness and collapses. Fainting is sometimes accompanied by brief clonic seizure activity, but this generally requires no specific treatment or investigation.
- Recovery of consciousness occurs within a minute or two, but clients may remain pale, diaphoretic and mildly hypotensive for several more minutes.
- To reduce the likelihood of fainting (and the possibility of injuries), consider the following measures to lower stress in those awaiting immunization:
    - Prior to immunization, ask client about history of fainting with previous immunizations.
    - Seat every client prior to immunization.
    - Avoid long line ups in mass immunization clinics
    - Prepare vaccine(s) out of view of recipients
    - Provide privacy during immunization
    - If anxious and pale, have client lie down with legs elevated. Reassure client.
    - If possible, ensure plenty of fresh air.
    - Apply cold wet cloth to face.
- If person was lying down, have them sit for a few minutes before standing.

If unconsciousness persists for more than 2-3 minutes, call 911/ambulance and proceed as per emergency treatment for anaphylaxis.

- People experiencing anxiety may appear fearful, pale and diaphoretic, and complain of lightheadedness, dizziness and numbness, and tingling of the face and extremities. If hyperventilation is evident, it may be helpful to have the client rebreathe into a paper bag until symptoms subside.
- Breath-holding spells occur in some young children when they are upset and crying hard. Facial flushing and perioral cyanosis deepens as breath-holding continues. Some spells end with resumption of crying, but others end with a brief period of unconsciousness during which breathing resumes. Similar spells may have been previously observed. No treatment is required beyond reassurance of the child and parents. Table 2.2 outlines the key differences between anaphylaxis and fainting.

TABLE 2.2: ANAPHYLAXIS VERSUS FAINTING (VASOVAGAL SYNCOPE)

	ANAPHYLAXIS	FAINTING
DEFINITION	• an acute systemic and potentially fatal allergic reaction to a foreign substance. IgE-mediated antibody induces histamine release from tissue mast cells.	• a temporary unconsciousness caused by diminished blood supply to the brain due to painful stimuli or emotional reaction.
ONSET	• usually slower, most instances begin within 30 minutes after immunization.	• sudden, occurs before, during, or shortly after immunization; recovery occurs within 1-2 minutes
SKIN	• flushed, red blotchy areas (not necessarily itchy) • itchy, generalized hive-like rash • tingling sensation often first felt about the face and mouth • progressive, painless swelling about the face, mouth, & tongue	• pale • excessive perspiration • cold, clammy
BREATHING	• sneezing, coughing, wheezing, laboured breathing • upper airway swelling (indicated by hoarseness and/or difficulty swallowing) possibly causing airway obstruction	• normal, or • shallow • irregular • laboured
PULSE	• rapid, weak	• slow, steady
BLOOD PRESSURE	• decreased	• decreased
SYMPTOMS & BEHAVIOURS	• uneasiness, restlessness, agitation • hypotension, which generally develops later and can progress to cause shock and collapse • not all signs/symptoms will be exhibited in each person; usually one body system predominates.	• fearfulness • light-headedness • dizziness • numbness, weakness • tingling of extremities • hyperventilation • sometimes accompanied by brief clonic seizure activity
GASTRO-INTESTINAL	• nausea and vomiting • abdominal pain, diarrhea	• nausea
OTHER SYMPTOMS	• loss of consciousness • progression of injection site reaction beyond hives and swelling	

Adapted from BC CDC Immunization Manual and Canadian Immunization Guide 2006.

2.3 Allergic reaction

Allergic reactions constitute a spectrum, the extreme end of which is anaphylaxis, but milder forms may involve both the dermatologic/mucosal (e.g., urticaria, pruritis, rhinitis) and/or the respiratory systems (e.g., upper airway swelling, respiratory distress). Anaphylaxis is set apart from simple allergic reactions by the simultaneous involvement of the cardiovascular system and loss of intravascular volume, as well as respiratory obstruction.

2.4 Injection site reactions

A mild local reaction resolving by itself within a few minutes does not require special observation. If swelling and hives occur at the injection site(s):

- **Keep client under direct observation for at least 30 minutes** to ensure the reaction remains localized
- Observe for any deterioration in condition
- If hives or swelling disappear, or there is no evidence of any progression to other parts of the body or any other symptoms within the 30-minute observation period, no further observation is necessary. Release the client from observation.
- If any other symptoms arise, even if considered mild (e.g., sneezing, nasal congestion, tearing, coughing, facial flushing) or if there is evidence of any progression of the hives or swelling to other parts of the body, administer epinephrine
- There is little risk to the unnecessary use of epinephrine, whereas delay in its administration (when required) may result in difficulty to treat anaphylaxis and in death
- Apply ice for comfort.

3.0 SUPERVISION OF VACCINEE POST - IMMUNIZATION

- Vaccine recipients and TB skin test recipients should be advised to remain under supervision for at least 15 minutes after immunization, regardless of whether or not they have had the particular vaccine previously; **30 minutes is a safer interval when there is a specific concern about possible vaccine allergy.** The risk of fainting is the more common reason to keep vaccinees under observation.
- Routine supervision should ensure that vaccinees remain within a short distance of the vaccinator with the instruction that they ask someone to obtain the nurse for them immediately for assessment if they feel unwell.
- Where vaccinees choose not to remain under supervision after immunization, they (or their parent/guardian) should be informed of the signs and symptoms of anaphylaxis and instructed to obtain immediate medical attention should symptoms occur.

4.0 ADMINISTRATION OF EPINEPHRINE

- Call 911 or ambulance.
- Administer epinephrine IM immediately. The most important step in the management of anaphylaxis is the immediate administration of aqueous epinephrine 1:1000. Failure to use epinephrine promptly is more dangerous than its improper use.
- IM injection of epinephrine into the thigh is the preferred route for administration.
- If administration into a thigh is problematic, epinephrine may be administered IM into the deltoid muscle of children ≥ 12 months of age and to adults.
- DO NOT inject epinephrine directly into an IM immunization site because it dilates blood vessels and speeds absorption of the vaccine (i.e. the offending allergen).
- BUT, if all limbs have been used for immunizations, epinephrine must still be administered to the patient intramuscularly. Epinephrine can be administered into a muscle close to where the immunization agent was administered. A minimum distance of 2.5 cm (1 inch) must be maintained between the injection sites of the immunization agent and the epinephrine.
- Injection can be made through clothing, if necessary.
- Repeat epinephrine at 10-minute intervals as needed (i.e. if breathing becomes more laboured or level of consciousness decreases) to a maximum of three doses.
- Alternate right and left thigh or arm sites for repeat doses of epinephrine (to maximize absorption of epinephrine).

GIVE EPINEPHRINE (1:1000 sol'n) – 0.01 ml/kg IM preferentially in the opposite limb to a maximum of 0.5 ml. The following approximate dosages may be used:	
AGE	EPINEPHRINE
2 – 6 months	0.07 ml
7 – 12 months	0.07 - 0.1 ml
13 – 18 months	0.1 - 0.15 ml
19 months – 4 years	0.15 ml
5 years	0.2 ml
6 – 9 years	0.3 ml
10 – 13 years	0.4 ml
≥ 14 years	0.5 ml

Manitoba Health Protocol for Management of Suspected Anaphylactic Shock – November 2007

5.0 ADMINISTRATION OF DIPHENHYDRAMINE HYDROCHLORIDE

- Give one dose of diphenhydramine hydrochloride 50 mg/ml IM as an adjunct to epinephrine when the person is not responding well to epinephrine, or to maintain symptom control in those who have responded (as epinephrine is a short-acting agent). **Its use is considered second-line therapy to epinephrine and should never be administered alone in the treatment of anaphylaxis.**
- Administer diphenhydramine hydrochloride once (maximum 50 mg) **IM**. It should be given at a site other than the vaccination and preferably at a different site to that in which epinephrine was given. However, if necessary, give diphenhydramine hydrochloride in the same thigh as that in which epinephrine was given.
- Diphenhydramine hydrochloride **IM** can be given at any time interval either after the initial or repeat doses of epinephrine, as indicated by the person's condition.

Give diphenhydramine hydrochloride (50 mg/ml) – to a maximum of 50 mg IM at a different site to that in which epinephrine was given. **Do Not Repeat**. The following approximate dosages may be used:	
AGE	**Diphenhydramine hydrochloride**
< 2 years	0.25 ml
2 – 4 years	0.5 ml
5 – 11 years	0.5 - 1.0 ml
≥ 12	1.0 ml

Manitoba Health Protocol for Management of Suspected Anaphylactic Shock – November 2007

6.0 OTHER CONSIDERATIONS

Position client in the recumbent position and elevate legs, as tolerated symptomatically. This slows progression of circulatory compromise, if present, by preventing orthostatic hypotension and helping to shunt effective circulation from the periphery to the head and to the heart and kidneys.

- Monitor respirations, pulse, and level of consciousness to guide medication use*.
- If person experiencing respiratory difficulty, elevate head and chest slightly.
- If airway is impaired, improve position by using head tilt, chin lift, or jaw thrust.
- If vomiting is likely, turn person to side lying position.

*Refer to table 6.1 for pulse and respiratory rates.

Table 6.1: Pulse and Respiratory Rates		
Age	**Heart (pulse) rate per minute, Upper Limit**	**Respiratory rate per minute, Upper Limit**
0-1 month	180	60
2-12 month	160	50
12-24 month	140	40
2-6 years	120	30
6-12 years	110	20
>12 years (adult)	100	20

Emergency Medicine: A comprehensive study guide. 6th ed (2004). McGraw Hill.

7.0 CLIENT TRANSPORT

Arrange for rapid transport to an emergency department. Since 20% of anaphylaxis episodes follow a biphasic course with recurrence of the reaction after a 2 – 9 hour asymptomatic period, hospitalization or a long period of observation is recommended for monitoring.

8.0 RECORDING

- Record administration of epinephrine and diphenhydramine hydrochloride. The "Drug Management of Anaphylaxis" can be used as a guide.
- Document in the client file
- Complete the Manitoba Health (Public Health Agency of Canada) "Report of Adverse Events Following Immunization", and forward to Medical Officer of Health and Regional Immunization Coordinator.
- Flag client's immunization record (Manitoba Immunization Monitoring System) with the consequent contraindication to future immunization with the implicated vaccine.

9.0 RESOURCES

- *Protocol for Management of Suspected Anaphylactic Shock* – Manitoba Health Communicable Disease Control Branch available on the IRHA Shared Server at B:\PublicHealth\Immunization\Anaphylaxis & Adverse Events

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SECTION V – ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI)

1.0 INTRODUCTION

An adverse event following immunization (AEFI) is any untoward medical occurrence in a vaccinee which follows immunization and which does not necessarily have a causal relationship with the administration of the vaccine. The adverse event may be any unfavourable and/or unintended sign, abnormal laboratory finding, symptom or disease (Public Health Agency of Canada Report of Adverse Events following Immunization User Guide – November 2009).

AEFIs should be reported when the event:

- **Has a temporal association with a vaccine**
- **Has no other clear cause at the time of reporting**: A causal relationship between immunization and the event that follows does not need to be proven and submitting a report does not imply or establish causality. Sometimes the vaccinee's medical history, recent disease, concurrent illness/condition and/or concomitant medication(s) can explain the event(s).

Of particular interest are those AEFIs which meet one or more of the following criteria:

- **Is of a serious nature**: A serious adverse event is one that is life threatening or results in death, requires hospitalization or prolongation of an existing hospitalization, results in residual disability or causes congenital malformation.
- **Requires urgent medical attention**.
- **Is unusual or unexpected**: An event that has either not been identified previously or one that has been identified previously but is, at current, being reported at an increased frequency. For additional information regarding unusual or unexpected events, please refer to the Canadian Immunization Guide which can be accessed on-line at http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php

If there is any doubt as to whether or not an event should be reported, a conservative approach should be taken and the event should be reported. For further information the PHAC User Guide: Report of Adverse Events Following Immunization can be accessed at http://www.gov.mb.ca/health/publichealth/cdc/docs/aefi_manual.pdf

2.0 CRITERIA FOR AEFI REPORTING

The Public Health Act of Manitoba (C.C.S.M. c. P210) requires a duty to report reactions as such: “within seven days after becoming aware of a reportable event, a health professional must report it in accordance with the regulations.” The Immunization Regulation 36/2009 outlines the reportable adverse events corresponding with the adverse event categories as defined by the Public Health Agency of Canada in 2009, as follows:

(a) a local reaction at or near the injection site

(b) anaphylaxis

(c) an allergic reaction of any of the following types:
- (i) skin or mucosal, either at or near the injections site or generalized,
- (ii) cardiovascular,
- (iii) respiratory,
- (iv) gastrointestinal;

(d) one or more of the following:
- (i) seizures,
- (ii) meningitis*,
- (iii) Guillain-Barré Syndrome*,
- (iv) Bell’s Palsy*,
- (v) paralysis other than Bell’s Palsy*,
- (vi) encephalopathy* or encephalitis*,
- (vii) hypotonic or hyporesponsive episode (age < 2 years),
- (viii) persistent crying (continuous and unaltered crying for more than 3 hours),
- (ix) rash,
- (x) arthritis
- (xi) intussusception*,
- (xii) thrombocytopenia*,
- (xiii) parotitis,
- (xiv) oculo-respiratory syndrome:

* as diagnosed by a physician

(e) A serious event not described in (a) to (d) above.

3.0 AEFI REPORTING PROCESS

The Public Health Agency of Canada 2009 "Report of Adverse Event Following Immunization" form is available from Manitoba Health (see 4.0 Resources) at http://www.gov.mb.ca/health/publichealth/cdc/docs/aefi_form.pdf
This form must be completed when an adverse event may be caused by immunization.

- The original report should be forwarded to the Regional Immunization Coordinator, and a copy should be kept with the immunization consent form (client record).
- The Immunization Coordinator reviews the report and sends the original to the Medical Officer of Health for review. The MOH reviews the report and makes recommendations for future immunization.
- The MOH returns the report to the Immunization Coordinator, who sends the report to Manitoba Health & Healthy Living and to the reporting PHN.
- The PHN follows up with the client or client's parent/guardian regarding MOH recommendations for further immunization.

Manitoba Health & Healthy Living forwards the reports to PHAC after personal identifying information has been removed. On occasion, reports may be submitted directly to PHAC by vaccine manufacturers, travel health clinics, pharmacists, physicians or the general public.

4.0 RESOURCES

- *Report of Adverse Events Following Immunization* available on the IRHA shared server at B:\PublicHealth\Immunization\Anaphylaxis & Adverse Events or available at http://www.gov.mb.ca/health/publichealth/cdc/div/info.html

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SECTION VI – STORAGE AND HANDLING OF BIOLOGICAL PRODUCTS

1.0 INTRODUCTION - THE COLD CHAIN

"Cold chain" refers to the process used to maintain optimal temperature conditions during the transport, storage and handling of vaccines, starting at the manufacturer and ending with the administration of the vaccine to the client.

Immunizing agents are sensitive biologic materials that are subject to gradual loss of potency from deterioration and denaturation. Loss of potency can be accelerated under certain conditions of transport, storage and handling and may result in failure to stimulate an adequate immunologic response. Biologicals may be inactivated by exposure to excess light or heat or freezing, depending on the nature of the product, the temperature reached and the duration of exposure. Freezing will reduce the potency of inactivated vaccines and exposure to heat and light can compromise the stability of live-virus vaccines. **Any loss of vaccine potency is permanent and irreversible. Damage from successive exposures to adverse conditions is cumulative**. It is important to know the correct storage conditions for each biological product and to ensure that each is kept under the recommended conditions. Protection of vaccine potency and stability is important.

2.0 GENERAL RECOMMENDATIONS

- **Maintaining the quality of biological products is the shared task of manufacturers, vaccine handlers and all health care professionals responsible for immunization delivery.**
- The Regional Immunization Coordinator is responsible for ensuring that all staff who handle vaccines are trained in cold chain procedures. The coordinator is also responsible for decision-making regarding safety and efficacy of vaccine following cold chain incidents.
- Each public health office should designate one staff member to be the primary vaccine coordinator and another staff member as a backup. The designated person will be responsible for ensuring that all vaccines are handled correctly, that procedures are documented, and that all personnel receive appropriate cold chain training.
- Each public health office should have written procedures for vaccine storage and handling to facilitate cold chain management by all staff.
- The optimum temperature for storing refrigerated vaccines is between +2ºC and +8ºC. A good temperature to set the vaccine fridge at is 5°C, as this allows for greater leeway for protection from temperature fluctuations.
- As a general principle, 1°C to 2°C is considered "refrigeration conditions", with due regard to the accuracy of the temperature reading device: no product needs to be discarded for a validated temperature in this range for an exposure of any

period of time, even for a series of exposures within the temperature range of 0°C to 2°C. Exposures in this range need **not** be reported as a cold chain incident. (BC Centre for Disease Control)

- When the temperature is in the 1°C to 2°C range, adjust the refrigerator temperature and restore the temperature to within the +2°C to +8°C range **immediately**.
- All biological products freeze at temperatures below 0°C; products that have been exposed to temperatures below 0°C should not be used. Consult with the Regional Immunization Coordinator, as there may be specific exceptions to this (e.g., lyophilized products.) See Section 5.0, Management of a Cold Chain Incident, for more information.

3.0 EQUIPMENT

The essential cold chain equipment needed to transport and store vaccines include:

- A dedicated refrigerator for storing biological products
- A freezer for storing ice or gel packs
- Temperature monitoring devices
- Insulated containers (coolers)
- Ice packs/gel packs
- Insulating material

3.1 Refrigerators

- Store biological products preferably in a purpose-built refrigerator, (also called a pharmacy, laboratory or industrial grade refrigerator.) See National Guidelines, Section 3, for detailed information on refrigerators. http://www.phac-aspc.gc.ca/publicat/2007/nvshglp-ldemv/section3-eng.php
- Domestic frost free refrigerators can be used, with the precaution that temperatures may fluctuate in different compartments of the refrigerator, and vaccines can only be stored in certain areas. For details, refer to national guidelines above.
- Bar fridges are not adequate for biological products storage.
- Refrigerators are “Vaccine Use” only. Do not store items such as food and beverages in vaccine refrigerators.
- The room in which the refrigerator is placed should have a thermostat or thermometer to measure the ambient (room) temperature.
- Close the refrigerator door tightly. Lock the refrigerator, or place the refrigerator in a room that can be locked, to prevent unauthorized access, product handling or refrigerator tampering.

- Maintain the refrigerator temperature between +2°C to +8°C. Set the temperature at +5ºC to provide a safety margin for temperature fluctuations.
- Place the refrigerator away from the wall or surrounding structures (according to manufacturer's recommendations) to provide proper ventilation and air circulation on all sides.
- Ensure the area around (including behind and under) the refrigerator is clean and dust free. This will help to ensure that the refrigerator is working at optimal levels.
- Protect the refrigerator from direct sunlight.
- Connect the refrigerator to a dedicated circuit that is not used for other appliances.
- Use a plug guard on the electrical outlet for the refrigerator to prevent accidental disconnection from power.
- Label the vaccine refrigerator's power-breaker switch in the electrical panel box: "VACCINE REFRIGERATOR - DO NOT DISCONNECT / DO NOT SWITCH OFF".
- Have a refrigerator maintenance check (cleaning coils, checking door seals) done regularly (at minimum, annually) and keep a record of maintenance service and repairs. Post the refrigerator maintenance repair telephone number on the refrigerator for easy accessibility.
- Check refrigerator seals quarterly to ensure cold air cannot leak out. If seals are brittle or torn arrange for replacement.
- When refrigerators are newly installed or just repaired, follow manufacturers' recommendations for establishing the appropriate temperature before placing vaccines into the unit.
- See national guidelines for a "maintenance" checklist: http://www.phac-aspc.gc.ca/publicat/2007/nvshglp-ldemv/resources-eng.php

3.2 Temperature Monitoring

- Use a constant temperature-recording device or digital minimum/maximum thermometer (with probe) to monitor both the current refrigerator temperature and the minimum/maximum temperatures.
- Thermometers should be calibrated to be accurate within +/- 1° C or better.
- Check equipment annually, or according to manufacturer's specifications, to ensure thermometer measurement is accurate, batteries are functioning, and cables/probes are undamaged. Maintain and change batteries as recommended by the manufacturer, keeping in mind warranty requirements.
- See the national guidelines for detailed information on temperature monitoring devices: http://www.phac-aspc.gc.ca/publicat/2007/nvshglp-ldemv/section3-eng.php
- Place the thermometer probe inside a vaccine box centrally (in the middle of the middle shelf) in the refrigerator, **not** at the back or near the door.

- Have extra thermometers (ideally min/max thermometers) available for use in coolers that are being used to store vaccines for several hours (e.g. for use at an off-site mass clinic.) It is not necessary to use a thermometer in small coolers used at a clinic work station.
- At the start and end of each workday, record the minimum and maximum temperatures reached since the last monitoring, on the **Fridge Temperature Monitoring Form** – see 6.0, Resources**.** Reset the min/max thermometer once you have recorded the temperatures.
- Retain completed forms in order to have a history of temperature maintenance for refrigerated biological products for a minimum of three years.
- Many biologicals orders shipped from the provincial vaccine warehouse to public health offices will contain an electronic monitoring device which provides time and temperature data for vaccine shipments from the warehouse to offices.
- Temperature Indicator Cards are visual markers, sensitive to either warm or cold exposures. The markers are activated and will change color when threshold temperatures are reached. The markers do not provide interpretation of product integrity.
- "Warm" indicators are available with different temperature threshold set points, and different run times (hours of use.) The Manitoba Provincial Vaccine Warehouse uses markers that activate after exposure to temperatures > 10°C. When the temperature threshold is reached, the background film melts, discoloring the paper red. Each circular window is stained incrementally red in relation to the exposure time above the threshold (e.g. top circular window stained after 2 hours, middle window after 12 hours, and bottom window after 48 hours.)
- Refer to 6.0, Resources, for the **IRHA Vaccine Cold Chain Algorithm** and 5.0 for management of vaccine exposures to temperatures outside of the appropriate range. No vaccine should be removed from cold chain conditions until consultation with the Regional Immunization Coordinator.

3.3 Insulated Containers

- Insulated containers (coolers) are used to transport quantities of vaccine off-site during one working day, or to store quantities of vaccine needed for immunization on site during a working day, thus avoiding frequent opening of the refrigerator.
- The cooler must be able to maintain vaccine temperature of +2°C to +8°C during transport and throughout clinics.
- The temperature inside the cooler is maintained with ice/gel packs, and insulating materials.
- The cooler should meet the following criteria:
  - It is large enough to store vaccines, ice/gel packs, and insulating material during transport.
  - The external surface material is strong and durable.

- The lid is tight fitting.

3.4 Ice packs/gel packs

- Keep a combination of frozen ice packs and refrigerated gel packs stored for use in packing coolers for off-site clinics.
- Set ice packs on their edge and allow space between them for air circulation in the freezer.

3.5 Insulating Materials

- Insulating materials are used as a barrier to prevent direct contact between vaccines and frozen packs.
- Insulating materials include flexible insulating blankets and gel packs at refrigerator temperature, crumpled packing paper, bubble wrap, or styrofoam peanuts.
- A layer of paper toweling is not sufficient as a barrier to protect vaccines from contact with frozen material.

4.0 HANDLING BIOLOGICAL PRODUCTS

4.1 Vaccine Delivery to Health Units

- Vaccine shipments require immediate attention. Unpack and refrigerate biological products immediately upon their arrival.
- Check for evidence of physical damage, open and examine shipping container and its contents for any signs of physical damage, freezing or excessive heat. If you notice evidence of damage, label the products as “Do not use”, quarantine in the refrigerator, and contact the Inventory Management Specialist at Manitoba Health at 204-788-6722 for directions about vaccine use.
- Check for temperature monitoring device/indicator and if there is one, follow monitoring device instructions.
- The national guidelines provide a resource for tracking vaccine inventory. See http://www.phac-aspc.gc.ca/publicat/2007/nvshglp-ldemv/resources-eng.php
- Cross check the contents with the packing slip to be sure they match. Insure all vaccine has been removed from the shipping container.
- Place the vaccine in the designated vaccine fridge and rotate stock.
- Report any discrepancies with the packing slip to the provincial vaccine warehouse **(204) 633-2621 or Toll Free (800) 665-7315.**
- Quarantine shipment in the refrigerator for recommended timeframe until the temperature monitoring device has been checked at the provincial vaccine

warehouse to ensure vaccine cold chain has been maintained (see 6.0, Resources, for the **Release Vaccines from Hold table**).

4.2 Vaccine Storage

- See 6.0, Resources, for **Organize Fridge**, for diagram illustrating placement of biological products in the refrigerator.
- "First in, first out": rotate vaccine stock according to expiry date (placing vaccine with the shortest expiry date at the front of the shelf, and longest expiry date at the back) so that vaccine closer to the expiration date will be used first.
- The expiry date is the date by which a vaccine or diluent should be used. When the date is marked as a month and year, the vaccine or diluent may be used up to and including the last day of the month. Note: some component vaccines and diluents may be assembled into one package with a labeled expiry date on the outer carton. This date is the shorter of the two dates of either the component vaccine or the diluent in the package.
- Check multidose vials which have been opened. Mutidose vials are dated when first opened, and should be used within 30 days of first puncture unless the product monograph specifies a shorter time period for use (e.g. some influenza vaccine in multidose presentation must be used within 7 days of first puncture.)
- Contact the Regional Immunization Coordinator for direction on all expired products – some product may be returned to provincial vaccine warehouse for credit.
- Vaccines that have experienced a cold chain incident and have been determined to be useable should be used at the first opportunity.
- Group the same biological products together and space the products to allow air circulation between rows.
- Keep all vaccines in their original packaging prior to use. Do not mix different lot numbers or expiry dates of the same vaccine product in the same package.
- Store vaccines only on the upper and middle shelves in the refrigerator.
- Refrigerator door shelves and crispers should never be used for vaccine storage as these areas are more susceptible to temperature fluctuations.
- Store sealed bottles of water in the refrigerator to provide cold mass that will help to maintain internal temperatures and delay temperature changes in the event of a power or refrigerator failure.
- Store flexible insulating blankets or gel packs that will be used as insulating material during vaccine transport in the refrigerator.
- Diluent for vaccines can be stored at room temperature to conserve refrigerator space, unless the product insert specifies refrigeration.
- Store epinephrine at room temperature (15°C to 30°C) and protect from heat, light and moisture. Do not store epinephrine in the refrigerator.
- Open the refrigerator door only when necessary, and close it as soon as possible.

4.3 Vaccine Orders

- To order biologics, use the "Biologics/Vaccine order form from Manitoba Health available at https://web2.gov.mb.ca/health/cdc/ivpd.html
- Review inventory on hand and order vaccines as needed. Order only one month's supply.
- Avoid over-ordering or early ordering. Do not stockpile vaccines. Any loss will be more costly in the event of a power outage or refrigerator failure, and the risk of wastage from expired product is increased.
- Alert staff when an order is placed, and when order is expected to arrive. All staff need to be aware of procedures to follow when a biologicals order is received and the Primary Vaccine Coordinator or designate is not available.

4.4 Principles of Vaccine Handling

- Keep vaccines in the refrigerator or in a cooler until ready to administer.
- Use small coolers at work stations during mass immunization clinics. This will reduce the number of times that the refrigerator or larger cooler will be opened and closed during the day, thus reducing temperature fluctuations and exposures to adverse conditions.

4.5 Transportation and Management of Vaccines for Clinics

- Consider the amount of vaccine to be transported, the external air temperature, and the length of time the vaccine will be in an insulated container. This will help to determine packing requirements.
- Packing vaccines for clinic use:
    - Keep vaccines in original packaging.
    - Place a thermometer with the vaccine in the cooler when vaccine will be in the cooler for more than 4 hours. Note: A minimum/maximum thermometer is recommended for monitoring temperature inside large coolers during mass immunization clinics.
    - Provide a protective barrier of insulating material between the vaccines and the frozen packs.
    - Place frozen packs at the top of the cooler.
    - See 6.0, Resources, for **Packing Cooler for Off-site Clinics**
- Packing configurations will vary on a seasonal basis. It is most important that vaccines do not freeze. In winter conditions, less ice may be needed to maintain the required temperature; more ice may be needed for summer conditions
- Maintain the packing configuration when removing vaccines from or returning vaccines to the cooler.
- Refrigerate diluent for 24 hours in the refrigerator if you are planning on transporting it in the cooler with the vaccines. Diluent that is not refrigerated

before being placed in a cooler may warm the temperature in the cooler. If you have not refrigerated the diluent, transport it separately from vaccines.

- Keep coolers out of direct sunlight. Do not place coolers in the trunk of the car where temperatures cannot be monitored. When weather temperatures are below +2°C, transport in a vehicle where the temperature can be kept higher than +2°C to avoid freezing. Do not place coolers by the car heater.
- Check the temperature readings hourly to ensure the vaccines are maintained within cold chain parameters.

5.0 MANAGEMENT OF A COLD CHAIN INCIDENT

- All biological products are licensed for use under storage conditions of +2°C to +8°C.
- Any temperature outside of the +2°C to +8°C range requires immediate action.
- Check that your thermometer is working correctly; you may need to change the battery. Check manufacturer's specifications for battery life.
- On the Temperature Log, record the date, time and three temperatures (the current refrigerator temperature, the minimum temperature reached since last check, and the maximum temperature reached since last check.) Also record the refrigerator dial setting. Reset the thermometer after recording these temperatures.
    - If the current refrigerator is malfunctioning, move all of the vaccines to a properly functioning, monitored refrigerator.
    - Adjust your refrigerator temperature setting and monitor the effect of this measure, or have the refrigerator serviced, and check that the temperature is between +2°C to +8°C before returning any vaccine to the refrigerator.
    - Place exposed vaccines in a container; clearly label as "DO NOT USE", and mark the date and time. Place this container with the exposed vaccines back into a functioning refrigerator, ensuring that the exposed vaccines are separate from any non-exposed vaccines. It is important that the exposed vaccines are returned to acceptable temperatures (+2°C to +8°C) as soon as possible.
    - Complete the Manitoba Health Cold Chain Failure Response Form https://web2.gov.mb.ca/health/cdc/ivpd.html (username cdc, password info). When a cold chain failure occurs, all sections of the *Cold Chain Failure Response Form* must be completed and faxed to the Manitoba Health, Communicable Disease Control (CDC) Branch at: (204) 948-2040.
    - Contact your Regional Immunization Coordinator for direction about use of the vaccines.
    - Do not discard any vaccines until this consultation and determination of use has been made.

- Clearly label biological products that have had a cold chain incident, but are subsequently deemed to be usable.

5.1 Power Failure

- Establish an office-specific emergency plan for power failures or equipment malfunction.
- Identify a back-up refrigerator that is accessible, monitored and functional at all times.
- On the Temperature Form, record the refrigerator temperature (minimum, maximum and current), room temperature, and time, as soon as possible after the start of the power failure. Reset the thermometer.
- Place a “DO NOT USE” sign on the refrigerator. Do NOT open the refrigerator except to remove vaccines for alternate storage.
- On average, the temperature in a powerless refrigerator will increase approximately +1°C per hour. The refrigerator is insulated and able to maintain its temperature, especially if it contains cold bottles of water.
- If power is expected to be restored within four hours or less, keep the vaccines in the refrigerator and keep the refrigerator doors closed.
- If a longer power outage is expected, or if the refrigerator temperature is going out of range quickly, move vaccines to a cooler with ice packs and insulating material. Take the vaccines to a facility that has a functioning monitored refrigerator (i.e. that has power or a back up generator) as per the local emergency plan.
- Continue to monitor and record refrigerator temperatures for the duration of the outage.
- Record the time and refrigerator temperatures (current, minimum and maximum) when the power is restored.
- Complete the Cold Chain Incident Form and contact your Regional Immunization Coordinator if products have been exposed to temperatures outside of the 0°C to +8°C range.

6 .0 RESOURCES

Listed below are available on the IRHA shared server at B:\PublicHealth\Immunization\Cold Chain resources:

- *Fridge Temperature Monitoring Form*
- *IRHA Vaccine Cold Chain Algorithm*
- *Release Vaccines from Hold table*
- *Organize Fridge*
- *Packing Cooler for Off-site Clinics*

SECTION VII – GENERAL CONSIDERATIONS

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SECTION VII – GENERAL CONSIDERATIONS

1.0 DISPOSAL OF SHARPS AND HAZARDOUS MATERIALS

Opened vials and ampoules (containing live, attenuated bacterial or viral products), needles, syringes and any other equipment contaminated with bodily fluids such as blood, should be treated as infectious and discarded in an approved and labeled sharps and biomedical waste container. Safe handling of sharps is necessary to prevent injuries that may result in contact with and transmission of pathogens, most notably Hepatitis B, C and HIV.

- Sharps containers should be located as to permit safe and convenient disposal of sharps.
- Sharps containers will not be left unattended during clinics in the community/school setting.
- Before moving or transporting a sharps container, the lid shall be securely in place. The sharps container should be placed in the trunk if transported in a vehicle.
- Sharps containers shall not be completely filled as overfilling may pose a hazard to the individuals using or discarding the containers. It is recommended good practice to fill sharps containers to no more than three-quarters of their usable volume unless specified otherwise by the container manufacturer. Sharps shall not be transferred from one container to another.
- The immunization provider will safely dispose of filled sharps containers as per Interlake RHA facility policy.

2.0 OCCURRENCE REPORTING

2.1 Introduction

- An “Occurrence” is an event, accident or circumstance that results in or could have resulted in an unintended, undesired outcome. The occurrences may result in injury to an individual and/or damage or loss of equipment or property.
- A “Critical Occurrence” not involving a client, is an occurrence involving substantial risk or harm to employees, medical staff, volunteers, students, visitors and others associated with the region, or to property, reputation or security.
- If a substantial risk/harm involves a client, refer to IRHA Policy GA-8-35 “Critical Clinical Occurrences, Reporting and Management”.

- The occurrence may be a major deviation from usual organizational practices or procedures, for example, a client fainting and hitting his/her head during an immunization procedure, disagreement of staff that affects the flow of an immunization clinic, a vaccine administration error, or a violation of the Personal Health Information Act (PHIA).

2.2 IRHA Policy GA-8-30 "Occurrence Reporting and Management" indicates:

The Occurrence Report is a standardized reporting form that is used throughout the Interlake Regional Health Authority. All staff shall:

- take action within the scope of their responsibilities to ensure client safety and to reduce any further loss or risk.
- provide immediate verbal notification to their immediate supervisor if the Occurrence is a Critical Occurrence.
- complete an Occurrence Report Form.
- forward the Occurrence Report Form to an immediate supervisor by the end of the working day/shift or in the case of a **Critical Occurrence**, forward immediately.

2.3 Occurrence process

- **Immediate Actions:**
  - Staff will assess and stabilize the situation
  - Call 911 if needed
  - Notify the school authority if appropriate
  - Notify the parent/guardian/next of kin as applicable
  - Notify the Immunization Coordinator or Public Health Program Manager if indicated**.**
- **First 24 Hours Actions:**
  - Complete the Occurrence Report Form
  - Original report to be sent to Immunization Coordinator within 24 hours
  - A copy of the report should be attached to the client's consent form
  - If the situation is a Critical Occurrence, the IRHA employee will complete the WCB Form, if indicated, and forward to Public Health Program Manager
- **Follow-up Actions:**
  - Follow-up is to be done soon after the incident (depending on the severity of the situation).
  - The parent/guardian is to be contacted for information/education/referral
  - Follow-up actions should be documented on the client record

3.0 POST-EXPOSURE TO BLOOD AND BODY FLUIDS

- An occupational exposure is an injury during which one person's blood or other high-risk body fluid comes in contact with another's body cavity, subcutaneous tissue, or non-intact, chapped or abraded skin, or mucous membranes. Injuries of concern include needlesticks, injuries from sharps and splashes or bites.
- All IRHA occupational exposures and near exposures will be reported to a supervisor**.**
- Employees of the IRHA and not of a facility (such as community health staff, etc) will be seen by a physician and forms sent to the nearest facility Infection Control Nurse.
- Note: All non-IRHA employees such as teachers, parent volunteers, etc. will be seen by a physician in the ER and managed according to the provincial protocol assuring urgent test results and treatment.

The following procedure is from IRHA Policy # IC-9-60 Post-exposure Protocol for IRHA Employees (Infection Control Manual – Staff Health):

3.1 Management of Exposure

- Encourage bleeding at the site of exposure
- Wash affected area with soap and water or antiseptic soap
- If splash is to eyes, wash out eye and area with cold water

3.2 Documentation

- Start the Post-Exposure Management Package (complete packages are available on each unit)*
  Package includes the following:

  a) Appendix 4; Exposed Post Exposure Management
  b) Appendix 4a; Source Post Exposure Management
  c) Appendix 4b; Near Exposure/Post Exposure report form
  d) Blood work requisitions, for source and exposed (Hep screen & HIV)
  e) MB Health fact sheet "Counseling Guidelines for Clients with Accidental Exposure to Blood and Body Fluids"; Nov, 2004

*Please refer to IRHA Policy #IC-9-60 for entire procedure.

- Notify Public Health Program Manager of incident.
- Complete WCB form and Occurrence Report.

3.3 Follow-up

- The parent/guardian is to be contacted for information/education/referral, if indicated.
- Document follow-up as indicated.
- Public Health Program Manager will coordinate follow-up with the IRHA employee on an as needed basis.

SECTION VIII – REFERENCES

American Academy of Pediatrics. (2006). *Red Book*: *Report of the committee on infectious diseases.* (27th ed.). Elk Grove Village, IL: Author.

British Columbia Centre for Disease Control – Communicable Disease Control, Immunization Program Manual – (2010) retrieved March 23, 2011 http://www.bccdc.ca/dis-cond/comm-manual/CDManualChap2.htm

Brown, S.G.A., Mullins, R.J., & Gold, M.S. (2006). Anaphylaxis: diagnosis and management. *MJA Practice Essentials – Allergy.* 185, (5) 283 – 289.

California Department of Public Health (2007). Comfort measures for infants. Retrieved May 11, 2011 from http://www.cdph.ca.gov/programs/immunize/Pages/ComfortMeasuresforInfants.aspx

Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices. Morbidity and Mortality Weekly Report. Dec 1, 2006/55 (RR15); 1 - 48. Retrieved May 10, 2011 from http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm

Centers for Disease Control and Prevention, Department of Health and Human Services (2007). Vaccine Storage and Handling Toolkit. Retrieved March 23, 2011 from http://www2a.cdc.gov/vaccines/ed/shtoolkit/

Centers for Disease Control and Prevention. (2007). *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Atkinson W, Hamborsky J, McIntyre L, Wolfe S, eds. 10th ed. Washington DC: Public Health Foundation.

Department of Health and Ageing (2005) National Vaccine Storage Guidelines: Strive for Five. Canberra, Australia. Retrieved June 2010 from http://www.health.gov.au/internet/immunise/publishing.nsf/content/provider-store

Ellis, A.K. & Day, J.H. (2000). Anaphylaxis: diagnosis and treatment. *Allergy Asthma*, 23-25.

Halperin, S. A. et al. (2006).How soon after a prior tetanus-diphtheria vaccination can one give adult formulation tetanus-diphtheria- acellular pertussis vaccine? *The Pediatric Infectious Disease Journal*, 25 (3), 195-200)

Immunization Action Coalition. (2001) *Comforting Restraint for Immunization*. Retrieved May 11, 2011 from http://www.immunize.org/news.d/comfrten.pdf

Ipp M, Taddio A, Sam J, Gladbach M, Parkin PC, (2007) Vaccine-related pain: randomized controlled trial of two injection techniques. *Arch Dis Child*, 92: 1105-1108 Retrieved May 11, 2011 from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2066084/

Gold, Ronald. *Your Child's Best Shot: A parent's guide to vaccination*, 3rd edition, Ottawa, Ontario: Canadian Pediatric Society: 2006

Grabenstein, John D. *ImmunoFacts: Vaccines and Immunologic Drugs*. St. Louis, MO: Wolters Kluwer Health, Inc.: 2006

Johnson, R.F., & Peebles, R.S. (2004). Anaphylactic shock: pathophysiology, recognition, and treatment. *Seminars in Respiratory and Critical Care Medicine,* 25 *(*6), 695-703.

Joint Task Force on Practice Parameters: American Academy of Asthma Allergy and Immunology; American College of Allergy Asthma and Immunology; Joint Council of Allergy, Asthma and Immunology. (2005). The diagnosis and management of anaphylaxis: an updated parameter. *Journal of Allergy and Clinical Immunology,* 115, S483-523.

Manitoba Health – Communicable Disease Control: Immunization Manual – Informed Consent Protocol, September 2003 Retrieved March 23, 2011 from https://web2.gov.mb.ca/health/cdc/ivpd.html

Manitoba Health – Public Health Act retrieved May 10, 2011 from http://www.gov.mb.ca/health/publichealth/act.html

Manitoba Health, Public Health Division – Communicable Disease Control: Cold Chain Protocol: Immunizing Agents and Biologics retrieved May 4, 2011 from http://www.gov.mb.ca/health/publichealth/cdc/coldchain.html

Manitoba Health, Public Health Division – Communicable Disease Control: Protocol for Management of Suspected Anaphylactic Shock. November 2007

Manitoba Health, Public Health Division – Communicable Disease Control: Information and Forms for Health Professionals. Report of Adverse Events Following Immunization Form and User Guide. Retrieved May 4, 2011 from http://www.gov.mb.ca/health/publichealth/cdc/div/info.html

Nicoll, L. H. & Hesby, A. (2002). Intramuscular injection: An integrative research review and guideline for evidence-based practice. *Applied Nursing Research*, 16(2): 149 – 162.

Potter, P.A., Perry, A.G., (2006) *Canadian Fundamentals of Nursing* (3rd ed.). Ross-Kerr, J.C., Wood, M.J. (Eds.). Toronto ON: Elsevier Canada.

Public Health Agency of Canada. (2006). Canadian Immunization Guide (7th ed.) Retrieved December 2010 from : http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php and http://www.phac-aspc.gc.ca/naci-ccni/index-eng.php Guide Errata and Clarifications, March 2008

Public Health Agency of Canada (2008).Final Report to Outcomes from the National Consensus Conference for Vaccine-Preventable Diseases in Canada. Retrieved June 17, 2011 from http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/08pdf/34s2-eng.pdf

Public Health Agency of Canada (2007). National Vaccine Storage and Handling Guidelines for Immunization Providers. Retrieved March 23, 2011 from http://www.phac-aspc.gc.ca/publicat/2007/nvshglp-ldemv/index-eng.php

Simons, F.E.R., Gu, X., Simons, K.J. (2001). Epinephrine absorption in adults: intramuscular versus subcutaneous injection. *Journal of Allergy and Clinical Immunology,* 108, 871-873.

Simons, F.E. R., Roberts, J.R., Gu, X., & Simons, K.J. (1998). Epinephrine absorption in children with a history of anaphylaxis. *Journal of Allergy and Clinical Immunology,* 101*,* 33-37.

Taddio A, Appleton M, Bortolussi R, et al. *Reducing the pain of childhood vaccination: an evidence-based clinical practice guideline. Canadian Medical Association Journal* 2010. DOI 10.1503/cmaj.101720. Fact sheets retrieved May 12, 2011 from http://www.sickkids.ca/pdfs/Learning/32832-CMAJ%20HELPinKIDS%202010%20Appendix%201%20parent%20tool.pdf http://www.sickkids.ca/pdfs/Learning/32833-CMAJ%20HELPinKIDS%202010%20Appendix%202%20clinician%20tool.pdf

Thibodeau, J.L. (1993). Office management of childhood vaccine-related anaphylaxis. *Canadian Family Physician,* 40, 1602 – 1610.

Tintinalli, J.E., Kelen, G. D., Stapczynski, J.S., Ma, O.J., & Cline, D.M. (2004). *Emergency Medicine: A Comprehensive Study Guide*. (6th ed.). New York, NY: McGraw-Hill.

Toronto Public Health. (2010). *How to reduce your child's pain from immunization*. Fact sheet retrieved May 11, 2011 from http://www.toronto.ca/health/immunization_children/howtoreducepain.htm

World Health Organization (2002) User's handbook for vaccine cold rooms and freezer rooms. Retrieved April 19, 2011 from http://www.who.int/entity/immunization/documents/WHO_VB_02.31/en